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ISBN: 978-1-4024-3136-4
LCCN: 2011932746
The Editors would like to thank our respective firms, Kleinfeld, Kaplan & Becker, LLP and Precision for Medicine, for supporting our efforts while writing the 2019 Edition of this book. We would also like to thank PLI for its dedication to publishing a *Medical Devices Law and Regulation Answer Book*; the contributing authors for their generosity in sharing their expertise with our readers; and the following authors for their contributions to the previous editions of the *Answer Book*: Jack Kent, M. Jason Brooke, Thomas Henteleff, Ronda Moore, Christine Vito, Ron Ginor, Jeff Harmes, Anthony T. Pavel, Jr., Himanshu Kashyap, William Kitchens, Ellen Flannery, Steve Kowal, Coleen Klasmeier, and Rebecca Wood. In addition, we wish to acknowledge Ms. Onel’s former firm, K&L Gates LLP, for its support on past editions of the *Answer Book* and Terry Enfield of Kleinfeld, Kaplan & Becker, LLP for her coordination of the work of our many collaborators which was invaluable in bringing the 2019 Edition of this book to fruition.

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**Kleinfeld, Kaplan & Becker, LLP (KKB)** is a law firm that specializes in issues affecting products regulated by the FDA—food, drugs, biologics, cosmetics, medical devices, dietary supplements, controlled substances, and tobacco products—as well as advertising law and other regulatory law governing consumer products and services. KKB is the oldest dedicated FDA boutique law firm in the United States and its attorneys have deep and expansive industry knowledge across all areas FDA regulates.

In addition to advising clients on FDA regulatory, compliance, and enforcement issues, KKB handles competitive trade disputes such as advertising claims challenges at the National Advertising Division and under the Lanham Act. KKB also provides transactional due diligence, advises businesses throughout the supply chain, and has a comprehensive administrative law practice, including the submission of petitions and comments relating to rulemaking and the resolution of administrative actions before the FDA, FTC, USDA, DEA, and other federal and state agencies. Clients include domestic and international...
manufacturers, suppliers, and distributors of FDA-regulated products, investors, industry associations, academic institutions, clinical research organizations, institutional review boards, hospitals, and medical practices. For more information about KKB, please visit www.kkblaw.com.

**Precision for Medicine** is a specialized scientific services partner dedicated to helping life science companies develop and commercialize next generation medical products. Precision offers a unique combination of expertise, scientific infrastructure and organizational scale to help guide products from development, through regulatory review, to market introduction and commercial success. Best-in-class teams of scientists and industry expertise and a specialized portfolio of services help clients accelerate research, enable market adoption, enhance patient outcomes and realize the full commercial potential of innovative products. The company, headquartered in Bethesda, Maryland, is part of Precision Medicine Group, a global company providing a complete range of scientific and commercialization services to the healthcare industry.

For more information about Precision for Medicine, please visit www.precisionformedicine.com.
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Foreword

Since the enactment of the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act, medical technology has evolved at an unprecedented rate. Innovation is being fueled by new concepts and ideas derived from virtually all fields of science and medicine. Simultaneously, legislation has expanded the roles and responsibilities of regulatory agencies to meet the challenges created by the imagination-stretching medical device industry. While the U.S. regulatory construct for medical devices has remained relatively constant, the expectations of our society, coupled with the complexities of an overburdened healthcare system, have resulted in a number of amendments to the statute, as well as new laws, regulations, and guidance documents. It is a constant challenge for individuals working in the field to keep pace with these changing, and sometimes divergent, regulatory requirements. Until now, there has been no single source of answers to the many common questions that surface when working within a complex system of somewhat overlapping and competing regulatory requirements for medical devices.

The contents of this book reflect that, while specialization is necessary to survive a complex regulatory environment, integration is essential if tomorrow’s leaders are to have a clear understanding of the challenges and opportunities before them. Application of this integrated knowledge is the basis for successful growth and survival of a medical device company. There is simply no better time to ensure that the proverbial forest is not obscured by the trees. To this end, this book brings together insights from the world’s leading experts in medical device law and regulation for the purpose of compiling a comprehensive overview of topics and questions of interest to virtually everyone doing business in the medical device sector.

Readers will find a compilation of far-ranging topics, from an overview of the U.S. legal framework for FDA device regulation to in-depth coverage of individual FDA programs that cover everything from conducting clinical trials, preparing successful premarket submissions, adhering to quality system requirements, and fulfilling post-market obligations. For those facing complexities related to in vitro
diagnostics and devices incorporating drugs, biologics, cell therapies, and software, experts familiar with these areas provide insight into what it takes to make these advances a reality. Perhaps even more importantly, other critical topics that are often overlooked in textbooks devoted to medical device issues are integrated to provide the reader a more global view of the realities that are encountered when operating in this heavily regulated environment. In this regard, the editors include chapters on specialized topics that have a marked impact on the medical device industry, such as intellectual property, product liability, and reimbursement. Nowhere is such a breadth of information presented in one answer book.

I suggest that this text be maintained for easy reference by all lawyers, consultants, and companies operating in the medical device sector, as well as all companies contemplating entry into the heavily regulated world of medical devices. After becoming familiar with its contents, readers will find it to be a ready source for valuable information on the topics that they will inevitably face, with answers to the most frequently encountered questions.

Philip J. Phillips
Phillips Consulting Group, LLC
Introduction

The Food and Drug Administration (FDA) regulates approximately 25 cents of every dollar that Americans spend on consumer and healthcare products. Medical devices occupy a fairly unique position within this category, in part due to the sheer number and variety of products sold in the United States (over 50,000), but also by virtue of the fact that medical devices have a relatively short life cycle and are regulated by FDA in a manner that recognizes and accommodates the public health importance of constant innovation. Medical devices can be as simple and familiar as toothbrushes, tongue depressors, syringes, and over-the-counter pregnancy tests, or as highly complex as sophisticated imaging technology, picture archiving systems (PACS), and life-sustaining products, such as heart valves, ventilators, and drug-eluting stents.

A seemingly endless stream of legal, regulatory, and compliance issues regularly confronts the medical device industry. The impact of FDA regulation is now commonly acknowledged to be the single greatest burden and risk to businesses developing and marketing medical devices. This comprehensive Medical Devices Law and Regulation Answer Book was designed to distill the essential elements of this complex regulatory environment and provide in a single resource a practical guide to the complexities of FDA regulation of medical devices, as well as important related topics not commonly included in surveys of the field.

The organization of this text broadly follows the typical life cycle of a device—starting at the premarket stage, continuing through FDA submissions and postmarket considerations, and onto commercialization and related considerations, such as licensing, reimbursement, and litigation.

- Chapter 1 provides an overview of the legal framework of FDA regulation of medical devices.
- Chapters 2–5 focus on premarket considerations, including clinical trials, IDEs, 510(k) and PMA submissions, 3D printed
devices, devices used with regenerative therapies, combination products, restricted devices, custom devices, and radiological products.

- Chapters 6–7 focus on manufacturing compliance, FDA inspections, and in vitro diagnostics.
- Chapters 8–11 focus on the Quality System Regulation, post-market issues, including device promotion, adverse event reporting, and international considerations.
- Chapters 12–21 focus on interacting with FDA and government enforcement and address device commercialization and related issues ranging from industry-supported scientific activities, intellectual property, licensing, reimbursement, and privacy to product liability, preemption, criminal enforcement, and oversight by other federal agencies.

Each chapter is organized to provide information by specific topic area, with each topic dissected into the questions that are most fundamental and frequently asked. The Question & Answer format was chosen to help readers quickly identify areas of interest and succinctly provide information that meets their immediate needs. All chapters include references to reflect the source of the information provided and facilitate a more detailed review of the topic. We have endeavored to ensure that all references in the text are current as of the date of publication, but we remind our readers that FDA law, regulations, and policy evolve over time.

The robust and dynamic U.S. medical device industry leads the world in developing new and important healthcare technologies. We are pleased and privileged to bring you this comprehensive and highly accessible reference book on FDA regulation of medical devices, authored by highly qualified experts in the field. It is our hope that this text will serve to orient and guide those new to the industry, and be a useful annotated resource for more experienced professionals.

Suzan Onel, J.D.
Karen M. Becker, Ph.D.
June 2018
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*Christopher J. Hanson*

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Edward C. Wilson, Jr. & Michael S. Heyl

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Christopher A. Bloom

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Susan P. Altman & Tyler Maddry

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*Patricia C. Shea*

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Patricia C. Shea

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Jennifer L. Bragg

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Steven Niedelman & Cathy L. Burgess

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<td>510(k)</td>
<td>Section of the Food, Drug, and Cosmetic Act that deals with premarket notification</td>
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<td>Accuracy</td>
<td>The level of agreement between the results of a test method and the gold standards</td>
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<td>ACMUI</td>
<td>Advisory Committee on the Medical Uses of Isotopes</td>
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<td>“the Act”</td>
<td>Food, Drug, and Cosmetic Act</td>
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<td>Adverse Device Event</td>
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<td>AdvaMed</td>
<td>Advanced Medical Technology Association (formerly known as the Health Industry Manufacturers Association, HIMA)</td>
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<td>Automatic External Defibrillator</td>
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<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<td>AIMD</td>
<td>Active Implantable Medical Device</td>
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<td>AIP</td>
<td>Application Integrity Policy</td>
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<td>AKS</td>
<td>Anti-Kickback Statute</td>
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<td>ANDA</td>
<td>Abbreviated New Drug Application</td>
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<td>ANPR</td>
<td>Advanced Notice of Proposed Rulemaking</td>
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<td>ANSI</td>
<td>American National Standards Institute</td>
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<td>APA</td>
<td>Administrative Procedures Act</td>
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<td>Ambulatory Payment Classification (CMS)</td>
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<td>Active Pharmaceutical Ingredient</td>
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<td>ARC</td>
<td>American Red Cross</td>
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<td>ARRA</td>
<td>American Reinvestment and Recovery Act of 2009</td>
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<td>ASR</td>
<td>Analyte Specific Reagents</td>
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<td>ATF</td>
<td>Bureau of Alcohol, Tobacco, and Firearms</td>
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<td>BBA</td>
<td>Balanced Budget Act of 1997</td>
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<td>BiMo/BIMO</td>
<td>Bioresearch Monitoring</td>
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<td>Blue Book</td>
<td>Office of Device Evaluation (CDRH) Policy Memoranda</td>
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<td>Public Health Security and Bioterrorism Preparedness and Response Act of 2002, also known as the Bioterrorism Act</td>
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<td>Corrective Action</td>
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<td>Competent Authorities (EU)</td>
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<td>CABs</td>
<td>Conformity Assessment Bodies/Compliance Assessment Bodies</td>
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<td>CAD</td>
<td>Control of Automated Processes</td>
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<td>C&amp;R</td>
<td>Corrections and Removals</td>
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<tr>
<td>CAPA</td>
<td>Corrective and Preventive Action (also spelled C&amp;PA)</td>
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<td>CBER</td>
<td>Center for Biologics Evaluation and Research</td>
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<td>CBP</td>
<td>Customs and Border Protection (DHS)</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>CDER</td>
<td>Center for Drug Evaluation and Research</td>
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<td>CDRH</td>
<td>Center for Devices and Radiological Health (FDA)</td>
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<tr>
<td>CE Mark</td>
<td>French phrase for Conformité Européenne</td>
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<td>CED</td>
<td>Coverage with Evidence Development</td>
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<td>CEO</td>
<td>Chief Executive Officer</td>
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<td>CFG</td>
<td>Certificate for Foreign Government/Certification for Foreign Government</td>
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# Table of Abbreviations

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<td>CFN</td>
<td>Central File Number</td>
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<tr>
<td>CFO</td>
<td>Chief Financial Officer</td>
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<td>CFR</td>
<td>Code of Federal Regulations</td>
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<td>CFSAN</td>
<td>Center for Food Safety and Applied Nutrition</td>
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<td>cGMP</td>
<td>Current Good Manufacturing Practice</td>
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<td>CHIP</td>
<td>Children’s Health Insurance Program</td>
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<td>CI</td>
<td>Clinical Investigator</td>
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<td>CIA</td>
<td>Corporate Integrity Agreement</td>
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<td>CLIA</td>
<td>Clinical Laboratory Improvement Amendments of 1988</td>
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<td>CLSI</td>
<td>Clinical and Laboratory Standards Institute</td>
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<td>CMC</td>
<td>Chemistry Manufacturing Controls</td>
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<td>CMD</td>
<td>Contractor Medical Director</td>
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<td>CME</td>
<td>Continuing Medical Education</td>
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<td>CMO</td>
<td>Chief Medical Officer</td>
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<td>CMP</td>
<td>Civil Money Penalty</td>
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<td>CMS</td>
<td>Centers for Medicare and Medicaid Services (formerly known as HCFA)</td>
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<tr>
<td>CoA</td>
<td>Condition of Approval</td>
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<td>COE</td>
<td>Certificate of Exportability (also spelled CE)</td>
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<td>COI</td>
<td>Conflict of Interest</td>
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<td>COMSTAT</td>
<td>Compliance Status Information System</td>
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<td>Compliance Programs</td>
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<td>Compliance Programs Branch</td>
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<td>CPG</td>
<td>Compliance Policy Guide</td>
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<td>CPSC</td>
<td>Consumer Product Safety Commission</td>
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<td>CPT</td>
<td>Current Procedural Terminology</td>
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<td>CRA</td>
<td>Clinical Research Associate</td>
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<td>CRC</td>
<td>Clinical Research Coordinator</td>
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<td>CRF</td>
<td>Case Report Form</td>
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<td>CRO</td>
<td>Contract Research Organization</td>
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<td>CSO</td>
<td>Consumer Safety Officer</td>
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<td>CSP</td>
<td>Coverage with Study Participation</td>
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<td>CT</td>
<td>Computed Tomography</td>
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<td>CTA</td>
<td>Clinical Trials Agreement</td>
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<td>CTI</td>
<td>Council on Technology &amp; Innovation</td>
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<td>CVM</td>
<td>Center for Veterinary Medicine</td>
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<tr>
<td>dba</td>
<td>Doing Business As</td>
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<td>DCIS</td>
<td>Defense Criminal Investigative Service</td>
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<td>DCMO</td>
<td>Division of Compliance Management Operations</td>
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<td>DCRND</td>
<td>Division of Cardiovascular, Respiratory and Neurological Devices (CDRH)</td>
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<td>DD</td>
<td>District Director</td>
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<td>DDMAC</td>
<td>Division of Drug Marketing, Advertising and Communications (CDER)</td>
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<td>DEA</td>
<td>Drug Enforcement Administration (U.S. Dept. of Justice)</td>
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<td>DFSR</td>
<td>Division of Federal-State Relations</td>
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<td>DGI</td>
<td>Directorate General for Industry (EU)</td>
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<td>DHF</td>
<td>Design History File</td>
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<td>DHHS</td>
<td>U.S. Department of Health and Human Services</td>
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<td>DHR</td>
<td>Device History Record</td>
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<td>DHS</td>
<td>U.S. Department of Homeland Security</td>
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<td>DME</td>
<td>Durable Medical Equipment</td>
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<td>DMEPOS</td>
<td>Durable Medical Equipment, Prosthetics, Orthotics &amp; Supplies</td>
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<td>DMR</td>
<td>Device Master Record</td>
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<td>DOD</td>
<td>Department of Defense</td>
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<td>DOE</td>
<td>Division of Enforcement (Office of Compliance, CDRH)</td>
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<td>DOJ</td>
<td>U.S. Department of Justice</td>
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<td>DPA</td>
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<td>DRGs</td>
<td>Diagnosis-Related Groups</td>
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<td>DSI</td>
<td>Division of Scientific Investigations</td>
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<td>DSMICA</td>
<td>Division of Small Manufacturers, International and Consumer Assistance (CDRH)</td>
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<td>DTC</td>
<td>Direct-to-Consumer</td>
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<td>DWPE</td>
<td>Detention Without Physical Examination</td>
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<td>EAR</td>
<td>Export Administration Regulations (U.S. Department of Commerce)</td>
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<td>EEA</td>
<td>European Economic Area</td>
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<td>EFTA</td>
<td>European Free Trade Association</td>
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<td>Electronic Identification</td>
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<td>EIR</td>
<td>Establishment Inspection Report</td>
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<td>eLEXNET</td>
<td>Electronic Laboratory Exchange Network</td>
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<td>eMDR</td>
<td>Electronic Medical Device Reporting</td>
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<td>Environmental Protection Agency</td>
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<td>ePHI</td>
<td>Electronic Protected Health Information</td>
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<td>Essential Prescribing Information</td>
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<td>European Patent Office</td>
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<td>EUCOMED</td>
<td>European Confederation of Medical Devices Associations</td>
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<td>FBI</td>
<td>Federal Bureau of Investigation</td>
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<td>FCA</td>
<td>False Claims Act</td>
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<td>Foreign Corrupt Practices Act</td>
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<td>Food and Drug Administration (DHHS)</td>
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<td>Food and Drug Administration Amendments Act of 2007</td>
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<td>Food and Drug Administration Modernization Act of 1997</td>
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<td>Federal Food, Drug, and Cosmetic Act (also spelled FFD&amp;CA/FD&amp;C/FDC Act)</td>
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<td>Food and Drug Export Reform and Enhancement Act of 1996</td>
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<td>Food and Drug Law Institute</td>
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<td>Food Defense Surveillance Assignment</td>
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<td>FDA establishment identifier</td>
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<td>FERN</td>
<td>Food Emergency Response Network</td>
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<td>FIFR</td>
<td>First-In-First-Reviewed</td>
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<td>FIFRA</td>
<td>Federal Insecticide, Fungicide, and Rodenticide Act</td>
</tr>
<tr>
<td>FMD</td>
<td>Field Management Directive</td>
</tr>
<tr>
<td>FMEA</td>
<td>Failure Mode and Effects Analysis</td>
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<td>FOIA</td>
<td>Freedom of Information Act</td>
</tr>
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<td>FR</td>
<td><em>Federal Register</em></td>
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<td>FSIS</td>
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<td>FTC</td>
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<td>FTEs</td>
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<td>FTO</td>
<td>Freedom-to-operate</td>
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<td>FURLS</td>
<td>FDA Uniform Registration and Listing System</td>
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<tr>
<td>FWS</td>
<td>U.S. Fish &amp; Wildlife Service</td>
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<td>GAO</td>
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<td>GCP</td>
<td>Good Clinical Practice</td>
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<tr>
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<td>Good Guidance Practices</td>
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<td>GPR</td>
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<td>GRAS</td>
<td>Generally Recognized as Safe</td>
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<td>GWQAP</td>
<td>Government Wide Quality Assurance Program</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>HACCP</td>
<td>Hazard Analysis and Critical Control Point</td>
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<td>HCFA</td>
<td>Health Care Financing Administration (DHHS; now known as CMS)</td>
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<tr>
<td>HCPCS</td>
<td>Healthcare Common Procedure Coding System</td>
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<td>HCT/P</td>
<td>Human Cellular and Tissue-based Products</td>
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<td>HCUP</td>
<td>Healthcare Cost and Utilization Program</td>
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<td>HGH</td>
<td>Human Growth Hormone</td>
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<td>HHS</td>
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<td>Health Insurance Portability and Accountability Act of 1996</td>
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<td>HIS</td>
<td>Hospital Information System</td>
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<td>HITECH Act</td>
<td>Health Information Technology for Economic and Clinical Health Act</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>Home Brew</td>
<td>Laboratory-developed tests used exclusively by that laboratory</td>
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<td>HSP</td>
<td>Human Subject Protection</td>
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<td>Humanitarian Use Device</td>
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<td>ICD</td>
<td>Implantable Cardioverter Defibrillator</td>
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<td>ICH</td>
<td>International Conference on Harmonization</td>
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<td>IDE</td>
<td>Investigational Device Exemption</td>
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<td>IECs</td>
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<td>IFE</td>
<td>Import-For-Export</td>
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<td>IFU</td>
<td>Instruction for Use</td>
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<td>IG</td>
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<td>IMF</td>
<td>International Mail Facility</td>
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<tr>
<td>IND</td>
<td>Investigational New Drug Application</td>
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<td>IOM</td>
<td>Institute of Medicine</td>
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<td>IOM</td>
<td>FDA Investigations Operations Manual</td>
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<td>Importer of Record</td>
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<td>IPO</td>
<td>Initial Public Offering</td>
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<td>IRB</td>
<td>Institutional Review Board</td>
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<td>IRO</td>
<td>Independent Review Organization</td>
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<tr>
<td>ISAP</td>
<td>Import Safety Action Plan or Action Plan for Import Safety</td>
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<td>ISO</td>
<td>International Standards Organization</td>
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<td>Independent Service and Repair Organization</td>
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<td>IT</td>
<td>Information Technology</td>
</tr>
<tr>
<td>IUO</td>
<td>Investigational use only</td>
</tr>
<tr>
<td>IVD</td>
<td><em>In vitro</em> diagnostic product</td>
</tr>
<tr>
<td>IVDMIA</td>
<td><em>In vitro</em> diagnostic multivariate index analysis</td>
</tr>
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<td>IVMD</td>
<td><em>In vitro</em> medical device</td>
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<td>LAS</td>
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<td>LASIK</td>
<td>Laser assisted in situ keratomileusis</td>
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<td>LCD</td>
<td>Local coverage decision</td>
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<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>LDT</td>
<td>Laboratory developed test</td>
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<td>LIS</td>
<td>Laboratory Information System</td>
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<td>LS/LS</td>
<td>Life supporting/life sustaining</td>
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<tr>
<td>LSSWG</td>
<td>Laser Systems Safety Working Group</td>
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<tr>
<td>MAP</td>
<td>Management action plan</td>
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<tr>
<td>MARCS</td>
<td>Mission Accomplishment and Regulatory Compliance Services</td>
</tr>
<tr>
<td>MAUDE</td>
<td>Manufacturer and user facility device experience database</td>
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<td>MCO</td>
<td>Managed care organization</td>
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<tr>
<td>MDA</td>
<td>Medical Device Amendments of 1976</td>
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<td>MDDs</td>
<td>Medical device directives</td>
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<td>MDDRP</td>
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<td>Medical Device Industry Initiatives</td>
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<td>MDP</td>
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<td>Medicare Prescription Drug, Improvement and Modernization Act of 2003</td>
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<td>MOU</td>
<td>Memorandum of Understanding</td>
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<td>Description</td>
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<tr>
<td>MPA</td>
<td>Multiple projects (human subjects) assurance</td>
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<tr>
<td>MPEP</td>
<td>Manual of Patent Examining Procedure</td>
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<td>Mammography Quality Standards Act of 1992</td>
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<td>MRA</td>
<td>Mutual recognition agreements</td>
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<tr>
<td>MRI</td>
<td>Magnetic resonance imaging</td>
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<td>MRT</td>
<td>Mail Review Team</td>
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<td>MSHA</td>
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<tr>
<td>NAD</td>
<td>National Advertising Division of the Council of Better Business Bureaus</td>
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<tr>
<td>NAF</td>
<td>Notice of Adverse Finding</td>
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<tr>
<td>NAI</td>
<td>No action indicated</td>
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<tr>
<td>NARC</td>
<td>National Advertising Review Council</td>
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<td>NCAs</td>
<td>National Competent Authorities</td>
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<td>NCCLS</td>
<td>National Committee of Clinical Laboratory Standards</td>
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<td>NCD</td>
<td>National Coverage Decision</td>
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<td>NCP</td>
<td>Nonconforming products</td>
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<td>NDA</td>
<td>Non-Disclosure Agreement</td>
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<td>NDA</td>
<td>New drug application</td>
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<td>NEISS</td>
<td>National Electronic Injury Surveillance System</td>
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<td>NEMA</td>
<td>National Electrical Manufacturers Association</td>
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<td>NF</td>
<td>National Formulary</td>
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<td>NIDPOE</td>
<td>Notice of Initiation for Disqualification and Opportunity to Explain</td>
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<td>Acronym</td>
<td>Description</td>
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<tr>
<td>NIH</td>
<td>National Institutes of Health (DHHS)</td>
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<td>NIOSH</td>
<td>The National Institute for Occupational Safety and Health</td>
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<td>NOC</td>
<td>Notice of Completion</td>
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<td>NPA</td>
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<td>National Program Office</td>
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<td>NPRM</td>
<td>Notice of Proposed Rulemaking</td>
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<td>NRC</td>
<td>Nuclear Regulatory Commission</td>
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<td>NSE</td>
<td>Not substantially equivalent</td>
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<td>NSR</td>
<td>Non-significant risk</td>
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<tr>
<td>NSRD</td>
<td>Non-significant risk device</td>
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<td>NTIS</td>
<td>National Technical Information Service (U.S. Department of Commerce)</td>
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<td>Official action indicated</td>
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<td>OC</td>
<td>Office of Compliance (CDRH)</td>
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<td>Office of Criminal Investigations (FDA)</td>
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<td>Office of Combination Products, Office of the Commissioner</td>
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<td>ODE</td>
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<td>Original equipment manufacturers</td>
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<td>Office of Foreign Assets Control (U.S. Department of Treasury)</td>
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<td>Office of Health and Industry Programs (CDRH)</td>
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<td>Office of the Inspector General (DHHS)</td>
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<td>Office of In-Vitro Diagnostic Device Evaluation and Safety</td>
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<td>Abbreviation</td>
<td>Description</td>
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<td>OMB</td>
<td>Office of Management and Budget</td>
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<td>OOS</td>
<td>Out of specification</td>
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<td>OPPS</td>
<td>Outpatient Prospective Payment System</td>
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<td>Order</td>
<td>Order of Need for Emergency Permit</td>
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<td>OSB</td>
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<td>Office of Science and Engineering Laboratories</td>
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<td>Occupational Safety and Health Administration</td>
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<td>OTC</td>
<td>Over-the-counter</td>
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<td>OTS</td>
<td>Off-the-shelf</td>
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<td>OUS</td>
<td>Out-of-U.S.</td>
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<td>PAD</td>
<td>Public access defibrillation</td>
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<td>P&amp;PC</td>
<td>Production and Process Controls</td>
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<td>PAP</td>
<td>Patient assistance programs</td>
</tr>
<tr>
<td>PAPS</td>
<td>Promotion and Advertising Staff (CDRH)</td>
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<td>Postapproval studies</td>
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<td>PBM</td>
<td>Pharmacy benefit manager</td>
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<td>PCT</td>
<td>Patent Cooperation Treaty</td>
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<td>PCTs</td>
<td>Practical clinical trials</td>
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<td>PDP</td>
<td>Product development protocols/principal display panel</td>
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<td>PDUFA</td>
<td>Prescription Drug User Fee Act</td>
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<td>PFS</td>
<td>Physician Fee Schedule</td>
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<td>PHI</td>
<td>Protected Health Information</td>
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<td>PHS</td>
<td>Public Health Service (DHHS)</td>
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<td>Description</td>
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<tr>
<td>PHSA</td>
<td>Public Health Service Act</td>
</tr>
<tr>
<td>PI</td>
<td>Package insert or product labeling</td>
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<td>Personal Information Protection and Electronic Documents Act</td>
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<td>P.L.</td>
<td>Public Law</td>
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<td>Product license application</td>
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<td>PMA</td>
<td>Premarket approval application</td>
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<td>PMN</td>
<td>Premarket notification (also 510(k))</td>
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<tr>
<td>PMOA</td>
<td>Primary mode of action</td>
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<td>PMS</td>
<td>Postmarket surveillance</td>
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<td>POS</td>
<td>Program operations staff</td>
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<td>PPC</td>
<td>Production and process controls</td>
</tr>
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<td>PPE</td>
<td>Personal protective equipment</td>
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<tr>
<td>ppm</td>
<td>Parts per million</td>
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<tr>
<td>Precision</td>
<td>The degree to which a given test result can be distinguished from another test result</td>
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<td>Quality Control</td>
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<td>Quality Control Unit</td>
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<td>Quality Management System</td>
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<td>Quality System</td>
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<td>Quality Systems Inspections Technique</td>
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<td>QSR</td>
<td>Quality System Regulation</td>
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<td>RA</td>
<td>Regulatory Affairs</td>
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<td>Description</td>
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<td>RAE</td>
<td>Remedial Action Exemption</td>
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<td>Research and Development</td>
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<tr>
<td>RBRVS</td>
<td>Resource-based Relative Value Scale</td>
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<td>RCHSA</td>
<td>Radiation Control for Health and Safety Act of 1968</td>
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<td>RCT</td>
<td>Randomized Controlled Trials</td>
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<td>ReGo</td>
<td>Reinventing Government</td>
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<tr>
<td>RFD</td>
<td>Request for Designation</td>
</tr>
<tr>
<td>RPM</td>
<td>Regulatory Procedures Manual</td>
</tr>
<tr>
<td>RTA</td>
<td>Refuse to accept</td>
</tr>
<tr>
<td>RUO</td>
<td>Research use only</td>
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<tr>
<td>SAL</td>
<td>Sterility Assurance Level</td>
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<tr>
<td>SCGD</td>
<td>Special Controls Guidance Documents</td>
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<tr>
<td>SE</td>
<td>Substantially equivalent/substantial equivalence</td>
</tr>
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<td>SEC</td>
<td>Securities and Exchange Commission</td>
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<tr>
<td>Sensitivity</td>
<td>The probability that a diagnostic test will yield a positive result when the disease or the target analyte is present</td>
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<td>SG</td>
<td>Study group</td>
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<td>SMDA</td>
<td>Safe Medical Devices Act of 1990</td>
</tr>
<tr>
<td>SMO</td>
<td>Site Management Organization</td>
</tr>
<tr>
<td>SOMDs</td>
<td>Software-only medical devices</td>
</tr>
<tr>
<td>SOPs</td>
<td>Standard Operating Procedures</td>
</tr>
<tr>
<td>SPC</td>
<td>Statistical Process Control</td>
</tr>
<tr>
<td>Specificity</td>
<td>The probability that a diagnostic test will yield a negative result when the disease or target analyte is absent</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>SR</td>
<td>Significant Risk</td>
</tr>
<tr>
<td>SRD</td>
<td>Significant Risk Device</td>
</tr>
<tr>
<td>SSA</td>
<td>Social Security Act</td>
</tr>
<tr>
<td>SSE</td>
<td>Summary of Safety and Effectiveness</td>
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<tr>
<td>SUD</td>
<td>Single-use device</td>
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<tr>
<td>TEP</td>
<td>Transatlantic Economic Partnership</td>
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<td>TMO</td>
<td>Trial Management Organization</td>
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<tr>
<td>TPLC</td>
<td>Total product life cycle</td>
</tr>
<tr>
<td>TRO</td>
<td>Temporary Restraining Order</td>
</tr>
<tr>
<td>UADE</td>
<td>Unanticipated adverse device event</td>
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<tr>
<td>UAI</td>
<td>Use as is</td>
</tr>
<tr>
<td>U.S.</td>
<td>United States</td>
</tr>
<tr>
<td>USC</td>
<td>United States Code</td>
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<td>U.S. Department of Agriculture</td>
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<td>USP</td>
<td>United States Pharmacopeia</td>
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<td>U.S. Patent and Trademark Office</td>
</tr>
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<td>Veterans Administration</td>
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<td>Voluntary action indicated</td>
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<tr>
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<td>Verification/validation</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>Warning letter</td>
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<tr>
<td>WLF</td>
<td>Washington Legal Foundation</td>
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