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Preface

When it comes to inventing, developing, and commercializing medical devices, companies will invariably come to an intersection between business, regulatory compliance, intellectual property, and the law. These areas are diverse, but an understanding of each is absolutely critical to the successful development of a new medical device product. With years of experience as consultants to entrepreneurs, doctors, and medical device companies, the authors of this book have recognized the guidance that is needed and have sought to furnish a guide to issues that are important to medical device companies as they work to bring new medical device technologies to market. Specifically, this book identifies and explains FDA regulatory pathways that are available to medical companies, provides a primer on intellectual property rights, and explores implementation strategies for medical device innovators.

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About the Book

FDA and Intellectual Property Strategies for Medical Device Technologies is intended to help guide readers through the U.S. Food and Drug Administration (FDA) regulatory compliance process that many medical devices must go through and is meant to shed light on some of the unique challenges medical device technology faces when it comes to intellectual property and regulatory strategy.

Part I of this book serves to provide the reader with a foundation of medical device development in the United States. It begins with a summary of the evolution of drugs and medical devices and how legislation evolved in the United States to protect the public. Examples of each type of medical device, how they are developed, and how the FDA regulates them are presented. Part I also provides recommendations for when and how to meet with the FDA as well as tips and tricks for successful and productive interactions at each stage in development. It includes a description of the content of the various medical device regulatory applications and summarizes a Sponsor's requirements once a device is actively being marketed.

Part II of this book provides a comprehensive overview of the most common forms of intellectual property rights. Part II also provides guidelines for how medical device companies can properly secure and implement their intellectual property rights. In Part II of this book, readers will learn how intellectual property rights can apply to their business by presenting examples from real-world companies, along with fictitious examples. Case studies are used throughout the book to demonstrate how intellectual property rights, management, and business all work together in industry. The examples throughout the book will relate to well-known companies and products that many readers will be familiar with.

Part III discusses how medical device companies can think about intellectual property strategy while exploring ways to avoid potential pitfalls and mitigate potential risks. Part III also describes commonly used tools that medical device companies typically use to successfully implement their regulatory strategy and delves into potential pitfalls while providing several strategies for avoiding or preventing regulatory compliance problems.

Examples and Illustrations Throughout This Book

Examples and illustrations will be used throughout this book. Some are real-world scenarios featuring well-known companies. Others are hypothetical scenarios. These are intended to enhance the reader's understanding of the subject matter contained in the chapters.

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Gerald B. Halt Jr., JD is president of Volpe and Koenig, P.C., where he counsels a global roster of clients ranging from individual inventors to Fortune 500 companies. With more than 25 years of experience, he focuses his practice on securing, enforcing, and licensing intellectual property rights in a wide array of technologies, including significant work with medical devices.

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[1] Disclaimer: In this book, Amber R. Stiles does not speak on behalf of the USPTO.

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Chapter 1
Introduction

The medical device industry is a booming area of technological development that is advancing with breakneck speed. Creative thought, in conjunction with ingenuity, can produce an innovative medical device that can have immense value for the medical device company that brings the product to market. An innovative medical device can enable healthcare providers to administer care more effectively and can provide patients with better quality care. Innovators are designing and developing new medical devices on a daily basis, but developing new, life-saving medical device technologies is not without it challenges. Medical device innovators in the United States must navigate hurdles in both the intellectual property space, as well as federal regulations by ensuring compliance with the regulations set out by the Food and Drug Administration (FDA). FDA compliance is often crucial to successfully bringing a medical device product to market, and securing intellectual property rights in the medical device technology is key to gaining and maintaining a competitive advantage.

FDA and Intellectual Property Strategies for Medical Device Technologies is intended to serve as a guide for readers who are involved in medical device development and commercialization. The book is broken down into three main parts:

I. FDA Strategies for Medical Device Technology
II. Overview of Intellectual Property Rights for Medical Device Technology
III. Implementation Strategies for Medical Device Innovators

1.1 Part I: FDA Strategies for Medical Device Technology

At first glance, federal regulation of medical devices can seem confusing and complex. For instance, medical devices are categorized by a class designation (Class I, II or III), but only some classes of medical devices are subject to FDA regulation. Furthermore, there are several different regulatory pathways to choose from (i.e.,

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application processes, such as PMA, 510(k), de novo, etc.), and determining which is applicable for your particular medical device can be confusing. Each regulatory pathway has various requirements that must be satisfied in order to obtain FDA approval, clearance or grant. To the uninformed, FDA regulation of medical devices can feel like a quagmire.

Part I: FDA Strategies for Medical Device Technology focuses on educating the reader on FDA regulation in the medical device realm. Each type of medical device class is explained, as is how the FDA regulates each type of device. Readers will develop an understanding about how strategy can play a role in obtaining FDA approval, clearance or grant and will learn a few helpful tips and tricks for streamlining the FDA review process. Readers will discover the differences between the various medical device regulatory applications, and will understand what is required of them as a medical device Sponsor during the application review process, as well as once the product is actively being marketed to the public.

1.2 Part II: Overview of Intellectual Property Rights for Medical Device Technology

Through the proper use of intellectual property law, one has a much better chance of transforming creativity and innovation into economic value. Intellectual property law recognizes a creator's rights in ideas, innovations and goodwill. Being intangible, intellectual property differs from real property (land) or personal property (physical possessions) that are secured, controlled, and protected using physical means such as fences, locks, alarms, and guards. Because intellectual property is a product of the mind, there is often no easy way to build a "fence" around it.

There are many intellectual property pitfalls that await the unwary. Different rules apply to different types of intellectual property ("IP") and you may forfeit your rights if you do not take the appropriate measures to secure and protect them. It is important to understand the types of IP protection and the respective rules that govern each type of IP.

1. *Patent*. Patents may be granted for the invention of any new and useful process, machine, manufacture or composition of matter or any new useful improvement thereof. A patent is a property right that grants the inventor or owner the right to exclude others from making, using, selling, or offering to sell the invention as defined by the patent's claims in the United States for a limited period of time.
2. *Trademark*. A trademark is a word, phrase, symbol, or design, or combination of words, phrases, symbols, or designs which identifies and distinguishes the source of the goods or services of one party from those of others. Trademarks promote competition by giving products corporate identity and marketing leverage.
3. *Copyright*. Copyrights protect original works of authorship fixed in a tangible medium of expression. Copyrighted works include literary, dramatic, and

musical compositions, movies, pictures, paintings, sculptures, computer programs, etc. Copyright protects the expression of an idea, but not the idea itself.
4. *Trade Secret*. Generally, a trade secret is any formula, manufacturing process, method of business, technical know-how, etc. that gives its holder a competitive advantage and is not generally known. The legal definition of a trade secret and the protection afforded to a trade secret owner varies from state to state.

Patents, trademarks, trade secrets, and copyrights all have a strong presence in the field of medical device innovation. Part II of this book provides an introduction to intellectual property law as applied to the medical device industry.

1.3 Implementation Strategies for Medical Device Innovators

Having an understanding of FDA regulation and IP rights is only half the puzzle—medical device innovators can also benefit from guidance on how to avoid potential pitfalls and how to mitigate or eliminate risk in the areas of FDA regulatory compliance and IP procurement, policing and enforcement.

Obtaining approval, clearance, or grant from the FDA is a good start, but medical device companies will have to demonstrate diligence in order to remain compliant with federal regulations once their product has been put on the market. Part III of this book will describe tools (such as, implementation of a robust quality management system) and techniques (for instance, meticulous record keeping) typically used by medical device companies to successfully implement their regulatory strategy.

Similarly, obtaining IP rights and registrations is only the first step in a successful IP strategy. Once IP rights are secured, it is important to monitor, police and exercise those rights. IP rights can be used offensively to initiate infringement litigation or encourage licensing activities; defensively to scare away potential competitors or to fend off litigation; or as a means of generating revenue streams through monetization. Part III of this book will also discusses how medical device companies can think about intellectual property strategy, while exploring ways to avoid potential pitfalls and mitigate potential risks.

Part I
FDA Strategies for Medical Device Technology

Chapter 2
General Overview of Development Process

2.1 History of Medical Device Regulation in the United States

In order to understand medical device development and regulation today, one must look back in history at the evolution of both drugs and medical devices, and how legislation evolved to protect the citizens of the United States. Device regulation is not as "new" as one might think. As with everything, guidance updates are required due to advancements in technology, unmet medical needs, and improved safety requirements.

During the 1800s, there were significant medical advances, including the discovery and effective use of anesthetic for surgery [1], the development of a rabies vaccine [2], and the use of x-rays in medical imaging [3]. However, during this same time period, medical quackery and "snake oil salesmen" gained prominence, and the use of products that were neither safe nor effective was rampant. Until 1906, drugs, medical devices, and foods went unregulated.

On June 30, 1906, the original Food and Drugs Act was passed by Congress and signed into law by President Theodore Roosevelt. This legislation focused on prohibiting interstate commerce of misbranded and adulterated foods, drinks, and drugs. Although the Food and Drugs Act did not include provisions for medical devices, this groundbreaking legislation started the US federal government's mission to protect Americans against threats from harmful medical substances and deceptive practices.

In 1938, the Federal Food, Drug, and Cosmetic (FD&C) Act contained provisions to extend regulation to therapeutic devices. This Act enabled the Food and Drug Administration (FDA) to evaluate the efficacy and safety of both drugs and medical devices. If such products were deemed ineffective and/or unsafe, the court system could be used to bring charges against the company marketing the product. However, because premarket testing, review, and approval were not required,

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products had to cause significant harm in order for the FDA to be able to act. The environment was ripe for disaster.

In 1962, such disaster struck outside the United States. Thalidomide, a sedative and sleeping pill popularly prescribed at the time, was reported to cause birth defects in thousands of babies in western Europe [4]. Dr. Frances Kelsey, an FDA medical officer, was proactive in keeping thalidomide off the US market. Importantly, the thalidomide disaster and the FDA's proactive approach to protecting Americans engendered significant public support for stronger regulations. In 1962, President Kennedy also proposed that medical devices should be regulated like drugs (but under different laws specific to device products), but because of the thalidomide disaster, it would be nearly 10 years before this proposal would materialize into law.

In 1971, the U.S. Public Health Service Bureau of Radiological Health was incorporated into the FDA. Their mission was to protect U.S. citizens against unnecessary exposure to radiation from electronic products in the home, industry, and the "healing arts." Five (5) short years later, laws were passed to ensure safety and effectiveness of medical devices, including diagnostic products, but not before the FDA was made aware of deaths associated with faulty pacemakers and Dalkon Shield intrauterine device injuries.

The 1976 Medical Device Amendments formally differentiated between drugs and devices (drugs exert their effect via a chemical reaction in the body, whereas devices do not). This amendment also required that devices be categorized into one of three classes with increasing controls based on their intended use and possible risk to patients:

- Class I devices pose the lowest risk to patients and include the use of general controls;
- Class II devices pose intermediate risk to patients and include the use of general controls with special controls, and
- Class III devices pose the greatest potential risk to patients and include the use of general controls with special controls but require pre-market approval.

The amendments also required manufacturers to register with the FDA and follow quality control procedures. This basic device classification is still used today and will be discussed in more detail later.

The FDA expanded their regulatory reach into long-term medical device safety with the Safe Medical Devices Act passed in 1990. This Act required nursing homes, hospitals, and other facilities to report to the FDA incidents of death, serious illness, or serious injury of a patient that were likely caused by a medical device. Importantly, this legislation also required device manufacturers to conduct formal postmarketing surveillance on devices implanted in the body that had the risk of causing serious harm or death upon failure. The Safe Medical Devices Act of 1990 empowered the FDA to order device manufacturers to recall faulty devices in the marketplace.

In 2002, major advances in FDA device regulation were codified. The Medical Device User Fee and Modernization Act (MDUFMA I), the foundational law of present day device regulation, enabled the FDA to assess fees from sponsors of

medical device applications. This same year, the FDA announced an initiative focused on FDA enforcement of current good manufacturing practices (cGMP). The goal of the cGMP initiative was to have risk-based manufacturing procedures along with process and product quality standards that were robust, but did not stifle innovation.

The success of MDUFMA I led to reauthorization in 2007 (the Medical Device User Fee Amendment [MDUFA II]), and again in both 2012 (MDUFA III), and 2017 (MDUFA IV). In each of these reauthorizations, the FDA published the user fee rates for Sponsor applications and updated their commitments to process improvement, enhanced guidance and support through formal and informal meetings, and decision-making performance goals. More information on each of these topics is provided in Chaps. 3, 4, and 5. MDUFA is eligible for reauthorization every 5 years, and will be up for renewal in 2022.

Importantly, the current state of device regulation is in significant flux. Although regulation tends to change slowly, the FDA has been particularly active in issuing revised and new medical device guidances in 2016 and 2017. Fiscal years 2018 and 2019 are anticipated to follow on this same trajectory. Thus, throughout this book, we will refer the reader to specific sections of U.S. Code (U.S.C.) and the U.S. Code of Federal Regulation (C.F.R.) and issued guidance documents current as of the writing of this book. However, the reader should conduct their own search of the device guidance documents on the FDA's website to ensure that you have the most current FDA thinking at your fingertips as you develop your medical device. You may also subscribe to the FDA's electronic notification program which will automatically send an email when the FDA issues a new guidance or updates an existing guidance.

2.2 Regulatory Definitions

2.2.1 What Is a Medical Device?

Section 201(h) of the FD&C Act [5] defines the term "device" as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

a. Recognized in the official National Formulary, the United States Pharmacopeia, or any supplement to them,
b. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
c. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, and

d. Not dependent upon being metabolized for the achievement of its primary intended purposes.

Example
Medical device examples include items as simple as elastic bandages, disposable gloves, stethoscopes, electric powered toothbrushes, wheelchairs, pregnancy test kits, and condoms, to more complex items such as implantable pacemakers, and artificial joints.

2.2.1.1 Components and Accessories

The FDA defines a component as any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device [6]. Examples of components can include wheels provided by a supplier to a wheelchair manufacturer, bedrails for hospital beds (to be assembled by the manufacturer and provided as a finished device prior to use by a hospital), and plastic housing for a glucose monitoring system. In all these cases, each of these components serve no direct medical purpose and the component is used by the device manufacturer in the assembly of the finish device. One point of caution—what may be regulated as a component for one device may be regulated as a device by the FDA for another product. Context is important when considering component classification.

FDA defines an accessory as a device that is intended to support, supplement, and/or augment the performance of one or more other (parent) devices [7]. Examples of medical device accessories include a tool used to accurately place a cranial nerve stimulator (parent device), bone cutting guides to assist in the proper placement of artificial joints (parent device), and chill packages and protective cases for insulin pen injectors (parent device).

2.2.2 What Is a Drug?

The FDA's definition of a drug as provided under Section 201(g) of the FD&C Act [8]:

a. articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;
b. articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
c. articles (other than food) intended to affect the structure or any function of the body of man or other animals, and

d. articles intended for use as a component of any articles specified in clause (a), (b), or (c).

Example
There are thousands of drugs currently approved by the FDA and many more under investigational development. Examples of FDA-approved drugs include acetylsalicylic acid (pain reliever), duloxetine (depression), oxycodone (pain reliever), sildenafil (erectile dysfunction), insulin (diabetes), ezetimibe (cholesterol), and fluticasone (asthma). Each one exerts their primary intended effect through chemical action within or on the body.

2.2.3 What Is a Biologic?

A biologic is defined by the FDA as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. Products that meet the drug definition and that also meet the definition of biological product are classified as biological products (see section 351(i) of the Public Health Service Act [9]).

Example
FDA-approved biological product examples include:

- Monoclonal antibody products such as adalimumab (rheumatoid arthritis), natalizumab (multiple sclerosis), and rituximab (non-Hodgkin's lymphoma);
- Vaccines such as rabies, smallpox, and influenza, and
- Cellular protein products such as talimogene laherparepvec (melanoma) and autologous cellular immunotherapy (refractory prostate cancer).

2.2.4 What Is a Combination Product?

Importantly, combination products are defined in 21 C.F.R. § 3.2(e). The term combination product includes:

a. A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity

("single-entity combination products", see 21 C.F.R. § 3.2(e)(1)). An example would be a prefilled insulin injector pen.

b. Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products ("co-packaged combination product", see 21 C.F.R. § 3.2(e)(2)). An example would be first aid kit that includes bandages as well as antibacterial ointment.
c. A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose ("cross-labeled combination products", see 21 C.F.R. § 3.2(e)(3)). An example would be a biologic product administered via a device that must have another drug prescribed at the same time to activate the biologic once it is implanted in the body (common in cancer therapies).
d. Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect (also "cross-labeled combination products", see 21 C.F.R. § 3.2(e)(4)). An example would be a surgical sealant that requires a specially designed light source to transform the liquid sealant into an adherent glue.

It is important to note that most combination products that include a drug or biologic (e.g., drug/device, biologic/device, drug/device/biologic) as part of the combination are usually regulated by the FDA as a drug. However, combination product submissions must contain all the necessary data and evidence to establish the efficacy and safety of both the drug and device components of the product.

Example
FDA-approved combination product examples include condoms with spermicide, glycopyrrolate inhalation solution (COPD), drug-eluting stents, recombinant human bone morphogenic protein-2 sponge (spine, oral-maxillofacial and orthopedic trauma surgeries), and sumatriptan nasal powder administered via an intranasal device (migraine). Interestingly, condoms with spermicide and drug-eluting stents are both regulated by the FDA as devices, whereas the other listed products were regulated as drugs or biologics with consults from the FDA's Center for Devices and Radiological Health (CDRH).