Fab Five

Legal Considerations for Medical Device Developers

1. What is the regulatory pathway to lawfully marketing a medical device?

Understanding how the FDA will regulate your device will guide the development process. An item that meets the definition of a "medical device" in §201(h)(1) of the Federal Food, Drug and Cosmetic Act will be regulated as a **Class I, II, or III device**, depending on the risk associated with the device and the level of controls necessary to safely use the product. Generally, most Class I devices may enter the market without premarket approval, most Class II devices require a §510(k) premarket notification, and Class III devices require full premarket approval (PMA). Certain products that incorporate drug or biologics components may be regulated as **drug-device** or **biologic-device combination products** under 21 CFR Part 3 and may require a new drug application or biologics license application. If applicants are uncertain of the appropriate pathway, they may request informal clarification from FDA or submit a **§513(g) Request for Information**.

2. When is a 510(k) premarket notification appropriate?

Technology companies seeking to market a Class I non-exempt or Class II medical device must submit a 510(k) premarket notification at least 90 days before introducing the device into commercial distribution. The key requirement is demonstrating that the new device is **substantially equivalent** to a **predicate device** in both intended use and technological characteristics. Devices that cannot meet this standard are regulated as a Class III device and require a PMA, unless the FDA agrees to a de novo request for classification as a Class I or II device. Applicants should follow FDA guidance for 510(k) determinations, including significant guidance released in September 2023 (see QR code on reverse for our summary).

3. What requirements apply to all medical devices regulated by FDA?

In addition to premarket review (required for some Class I devices, most Class II devices, and all Class III devices), all medical manufacturers must **register** the establishments that manufacture or prepare devices (21 CFR Part 807) and **list** the medical devices distributed in the U.S. (21 CFR Part 807). Post-market requirements include **reporting adverse events and device malfunctions** (MDR reporting, 21 CFR Part 803), **device tracking and unique identifier marking** (21 CFR Parts 821 and 830), **post-market surveillance** (21 CFR Part 822), and ensuring that manufacturing complies with the **Quality System Regulations** (QSRs, 21 CFR Part 820).

4. What requirements apply to clinical studies of a device in human subjects?

Sponsors must obtain approval from an **institutional review board (IRB)** of the study protocol, ensure that each subject provides **informed consent**, and comply with the FDA's **investigation device exemptions** (IDE) regulations, 21 CFR Part 812. **Significant risk devices**, as defined in 21 CFR §812.3(m), also require FDA approval of an IDE application before the study can begin.

5. What steps should medical device developers take to protect intellectual property?

To avoid infringement, developers should conduct a **patent search** and consider a **freedom-to-operate analysis**. Developers should also seek patent protection for all inventions that are patentable (**novel**, **useful**, and **non-obvious**). They may also seek further **trademark** and **copyright** protection (particularly important for medical device software) and take appropriate steps to protect **trade secrets**.

VENABLE LLP

About Venable's Life Sciences Team

Venable provides comprehensive legal services to the full range of life science sector participants, from fast-growing and emerging startups to large public companies and academic and research institutions. We also counsel contract research organizations (CROs), contract development and manufacturing organizations (CDMOs), and investor and funding institutions. These organizations that make up the pharmaceutical and biotechnology ecosystem interact not only with one another, but also with various government agencies and the courts. Regardless of the interaction within this varied space, Venable attorneys are well prepared to advise on a variety of legal needs.

Our professionals partner with clients working in a wide variety of life sciences technologies, including emerging drugs and biologic therapies, bioinformatics systems, laboratory instrumentation, and medical devices. Whether the issue relates to small-molecule drugs, biologics, cell and gene therapy, vaccines, medical devices, or human cellular and tissue products, our professionals are well versed in the technology and possess the experience and insight necessary to achieve our clients' goals.

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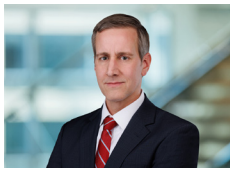

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