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CLS BULLETIN

MedTech Spotlight

This issue of the CLS Bulletin focuses on the MedTech sector. Thank you to our member companies who share how they're delivering the best care to the right patients, how they're staying ahead of the regulatory and market dynamics, and ensuring patients have access to life-changing technologies.

CONTRIBUTING ORGANIZATIONS

Medtech Primer on the FDA Regulatory Landscape

Submitted by Sonia Nath, Cooley Partner, specializing in FDA Regulatory matters

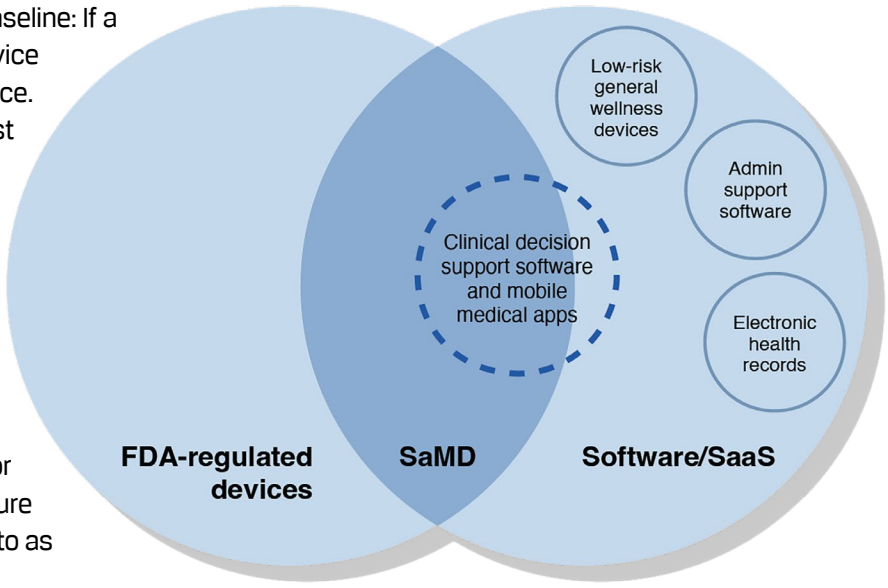
FDA medtech regulation 101: What is a 'device'?

Medtech companies are subject to FDA regulation as medical device manufacturers if their products satisfy the "device" definition in the Federal Food, Drug and Cosmetic Act (FDCA). As that definition[1] explains, if a product is intended to diagnose, cure, mitigate, treat or prevent a disease, or is intended to affect the structure or any function of the body, it is regulated by FDA as either a drug or a device.[2] If the product achieves its primary intended purpose through chemical or metabolic means, it is a drug; all other such medical products are devices under the FDCA.[3]

Software as a medical device (SaMD)

The FDA's general approach to the regulation of software begins with this regulatory baseline: If a software product meets the FDCA's device definition, it may be regulated as a device. But in 2016, with the passage of the 21st Century Cures Act, Congress excluded from the device definition certain software functions, including, among others, low-risk general wellness devices, certain mobile medical applications, administration support software, electronic health records, and certain software functions intended to provide decision support for the diagnosis, treatment, prevention, cure or mitigation of disease, often referred to as clinical decision support software.[4]

Additionally, in various guidance documents, the FDA announced its intention to exercise enforcement discretion – meaning that it could regulate but chooses not to at this time – for certain software functions, such as software that helps patients self-manage a disease or condition without providing specific treatment or treatment suggestions; automates simple tasks for healthcare providers; provides easy access to information related to patients' health conditions or treatments; and performs simple calculations routinely used in clinical practice.[5] While they do not create legally enforceable rights or obligations, the FDA's publicly announced enforcement policies add further complexity to the regulatory landscape for SaMD, as depicted below.



[1] 21 USC § 321(h).

[2] 21 USC §§ 321 (g), (h).

[3] *Id.*

[4] 21 USC §§ 321(h), 360j(o); see also Guidance for Industry and FDA Staff, Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act (Sept. 27, 2019), *available at* https://www.fda.gov/media/109622/download#:~:text=(Section%20520(o)(4,prevention%20of%20disease%20in%20humans.

[5] *See* Guidance for Industry and FDA Staff, Policy for Device Software Functions and Mobile Medical Applications (September 27, 2019), *available at* https://www.fda.gov/media/80958/download.

Device regulatory requirements and fees

After determining whether a product is subject to FDA oversight based on its intended use and the regulatory framework identified above, the next step is to determine the applicable regulatory requirements.

For products regulated by the FDA as devices, these regulatory hurdles are determined based on the level of risk presented by the device – from Class I (the lowest-risk devices) to Class III (the highest-risk devices). The below table summarizes these requirements.

Device classification	Risk level	Regulatory controls	FDA premarket submission	Documentation required for software premarket submissions	User fees for FY 2022[1]
Class I	Lowest risk (Presents minimal potential for harm)	General controls Quality System regulation (QSR)/Device current good manufacturing practice requirements (cGMPs) (unless exempt)	Exempt	N/A	N/A
			510(k)	Basic documentation or enhanced documentation, depending on device risk	510(k) application fee – $12,745[2] Annual establishment registration fee – $5,672
			De novo		De novo classification request fee – $112,457[3] Annual establishment registration fee – $5,672
Class II	Moderate risk (Presents higher risk than Class I devices)	General controls Special controls (if available) QSR/cGMPs (unless exempt)	Exempt	N/A	N/A
			510(k)	Basic documentation or enhanced documentation, depending on device risk	510(k) application fee – $12,745 Annual establishment registration fee – $5,672
			De novo		De novo classification request fee – $112,457 Annual establishment registration fee – $5,672
Class III	Highest risk (Sustains or supports life, is implanted, or presents potential unreasonable risk of illness or injury)	General controls Premarket approval (PMA) QSR/cGMPs	PMA	Enhanced documentation	Annual establishment registration fee – $5,672 PMA fee – $374,858[4]

[1] These fees generally are updated on a yearly basis.

[2] The 510(k) small business fee is $3,186.

[3] The de novo classification request small business fee is $28,114.

[4] The PMA small business fee is $93,714

The FDA generally requires valid scientific evidence to support a PMA, and will determine whether such evidence is sufficient to demonstrate reasonable assurance that a device is safe and effective for its conditions of use.[6] Depending on the nature and risk associated with the device for its intended use, the amount, type and source of the valid scientific evidence considered by the FDA can vary, as well as the regulatory requirements to collect such data.[7]

Medtech companies are well served to understand the FDA regulatory framework and how it can apply to their technology.

The 510(k) submission process is much shorter and faster, and requires only that a manufacturer demonstrate that its product is "substantially equivalent" to a predicate device, which is a legally marketed device that is similar, though not necessarily identical, to the new device.[8] The FDA requires differing levels of documentation for premarket submissions of device software functions – enhanced or basic documentation – depending on risk categorization. Enhanced documentation includes premarket submissions for, among others, devices classified as Class III, devices that are constituent parts of combination products, and devices where flaws could present a probable risk of death or serious injury. Any premarket submissions of device functions that do not fall within the enhanced documentation requirements may proceed with basic documentation.[9]

Medtech companies are well served to understand the FDA regulatory framework and how it can apply to their technology. Early engagement on these issues as a part of the overall business strategy can help a medtech company address and plan for regulatory hurdles at the outset, paving the way for successful product development, testing and launch.

[6] 21 CFR § 860.7.

[7] 21 CFR Part 812.

[8] 21 CFR §§ 807.87, 807.90, 807.100.

[9] *See* Guidance for Industry and FDA Staff, Content of Premarket Submissions for Device Software Functions (Nov. 4, 2021), *available at* https://www.fda.gov/media/153781/download.

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