

If your medical device requires FDA 510k clearance but you put it on the market without a 510k, what happens?

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By Michael H. Cohen

If your medical device requires FDA 510k clearance but you put it on the market without a 510k, what happens? Many clients have asked us: do we have a medical device? Do we need to submit a 510k? What happens if we don't file a 510k submission? Can we fly under the FDA radar?

Bob has a new consumer product, consisting of an antenna and a receiver, which “beam information at the quantum level” to sync patients’ brainwaves and help patients heal. Anecdotally, the product has been wildly successful. Bob has 50 distributors across the country, and consumer testimonials about remarkable results, from reversing hearing loss to recovering from neurological conditions.

Must Bob file a 510k?

To properly advise Bob, we have to go back to the definition of a medical device, review classification of devices, talk about the intended use doctrine and labeling, and let Bob know about FDA’s enforcement options.

Medical Device Definition

The first question is whether you have a medical device.

Look to the definition. A medical device is:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) 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

(3) 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 which is not dependent upon being metabolized for the achievement of its primary intended purposes.

One of the keys here is whether the intended use of the product is for diagnosis or treatment of disease.

Remember that FDA has announced it will be more hands-off if you have a low-risk, general wellness product.

The product must be intended for only general wellness use, and must present a very low risk to users' safety. For example: exercise equipment, audio recordings, video games, software programs, and other products commonly available from retailers — again, provided the intended use is not to diagnose or treat cancer, obesity, diabetes, hypertension, migraines, or any other disease or condition.

General wellness can include: maintaining or encouraging a general state of health or a healthy activity, or, associating the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions. For example, claims can be made about weight management, physical fitness, stress management or relaxation, sleep management, or even enhancing flow of *qi*.

Sometimes it can be difficult to determine whether the intended use is diagnostic or treatment-oriented, as opposed to something else such as “general wellness.” In such cases, it's best to contact FDA lawyers who can advise on whether you have a regulated medical device.

510k v PMA

The next step is regulatory classification.

Class I devices typically are **exempt** from premarket review requirements. Class II devices usually require a 510k, while Class III devices usually require a PMA.

The 510k has a lower regulatory burden than the PMA, in that the 510k must demonstrate that the medical device is **substantially equivalent** to a legally marketed “predicate device.” This boils down to the new medical device having either the same **technological characteristics** as the predicate device (including appropriate clinical or scientific data, if deemed necessary by FDA), or, having different technological characteristics but essentially being as safe and effective.

The PMA is not a comparative submission, but rather must demonstrate that the medical device is safe and effective in and of itself.

During research and development of a new device, or of a new use for an existing device, manufacturers collect safety and effectiveness data to support their PMA or 510k by, among other things, conducting clinical trials. Before starting the clinical trial, the manufacturer must obtain an approved investigational device exemption (IDE).

OTC Medical Device vs. Prescription Medical Device

OTC medical devices must include in their labeling, “adequate directions for use” which inform the layperson how to use the device safely and for the purposes for which it is intended.

This includes intended use; quantity of dose; frequency, duration, time, route or method, of application or administration; and preparation for use.

Prescription medical devices need not have adequate directions for use on the label. Prescription devices must be prescribed under the supervision of a licensed practitioner, and the label must include: “Rx only” or “Caution: Federal law restricts this device to sale by or on the order of ” (physician, dentist, veterinarian, etc.).

Adulteration and Misbranding

The federal Food, Drug & Cosmetic Act (FDCA) prohibits adulteration and misbranding.

A device is **adulterated** if there is something wrong with it that makes it unsafe and/or ineffective. For example, the device was made under unsanitary conditions or did not comply with the requirement for PMA approval.

A device is **misbranded** if there is something wrong with its **labeling** that could lead to unsafe or ineffective use. This includes false or misleading advertising, inadequate instructions for use, or failure to obtain the required 510k clearance.

As well, a device that requires 510k clearance but lacks such clearance is considered by operation of law to be a Class III device that requires a PMA, and therefore is also **adulterated**. (21 USC 513(f)(1)).

And, a device that is “about to be significantly changed or modified in design, components, method of manufacture, or intended use” (21 C.F.R. § 807.81(a)(3)) requires a 510k. Significant changes include: (1) a change or modification of the device that could significantly affect the safety or effectiveness of the device; or (2) a major change or modification in the intended use of the device.

The bottom line is that failing to submit a PMA or 510k when required for a medical device, is illegal and can trigger FDA enforcement action.

Penalties

What can FDA do?

Civil monetary penalties (CMPs) have a maximum penalty of \$15,000 per violation, not to exceed \$1 million for all violations in a single proceeding.

FDA can issue prior warnings before more serious enforcement.

Prior warnings can include:

- FDA warning letter
- FDA civil suit, administrative action, or other regulatory correspondence
- Notification by other state, municipal, or federal agencies involving the same or similar violations
- **FDA-483** (list of inspectional observations) provided by an FDA investigator at the conclusion of an inspection
- Discussion of objectionable conditions by FDA investigator with firm, as documented in the 483
- Verbal notification from FDA to top management
- Written or oral advisory communication by FDA
- Industry meetings during which FDA discusses violations, if firm’s attendance is documented

FDA’s current policy is that will usually provide prior warning before taking more serious enforcement action, but there are exceptions—notably, patient harm. FDA has a matrix for CMP fees, and will look at factors including:

- Nature of violations
- Circumstances
- Extent of violations
- Gravity (including patient harm)
- Ability to pay
- Effect on continued business
- History of prior violations
- Degree of culpability
- Other factors “as justice may require”

In its Guidance for FDA Staff, *Civil Money Penalty Policy*, FDA states that civil monetary penalty (CMP) cases “should serve to eliminate the profit from violative activity and/or to provide non-compliant firms with the financial incentive to correct violations.”

When a firm markets a device without required 510k clearance, the Guidance states, FDA usually documents prior warning of the violation, before imposing CMP, *unless* the violations represent a danger to health or are egregious in nature. Further, persons who are repeat violators (including those that fluctuate between being ‘out of compliance’ and ‘in compliance’ from one inspection to the next) may be good candidates for CMP action.

FDA may also impose CMP for promotion and advertising violations, failure of sponsors to meet IDE reporting requirements, or failure of clinical investigators to submit completed case reports.

Interestingly, the Guidance states that where in the past, FDA has used seizure or injunction for **low-risk devices**, FDA now will likely impose civil monetary penalties.

In cases where there has been fraud or other criminal activities, FDA’s Office of Criminal Investigation (OCI) may investigate. Should the investigation reveal evidence of criminal activity, FDA would work with the Department of Justice for possible prosecution of those involved. For misdemeanor violations, the government need not show criminal intent. An FDCA misdemeanor may be punished by a maximum of year in prison and a fine of \$100,000 for an individual, \$200,000 for a corporation. Felonies involve violations where there was “intent to defraud or mislead,” or a repeat offense. Company officers can be held personally (criminally) responsible in both criminal prosecution and monetary proceedings.

Back to Bob

One item that’s critical in Bob’s marketing is that he targets his product toward patients with a variety of named conditions. FDA can easily search for these terms online and find Bob’s products.

Bob has to be careful not to make diagnostic or therapeutic claims for his products. He should monitor the testimonials his company posts, *or LIKES* on social media, as these too could indicate a diagnostic or therapeutic intended use.

If Bob has a medical device, we will need to find out whether it is Class I, II or III.

We’ll need to know more about Bob’s product. He may have a **biofeedback device** (21 CFR 882.5050): “an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient’s physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that he patient can control voluntarily these physiological parameters.”

FDA regulates a **biofeedback device** as a Class II device *if* it is a prescription battery-powered device that is indicated for **relaxation training and muscle reeducation**. Otherwise, the device may be Class III.

When Bob talks about brainwave optimization he may be indicating a different mechanism and intended use than when he talks about “quantum” effects. Bob may or may not have a general wellness, low-risk medical device.

As well, Bob must have substantiation for the claims he makes regarding efficacy. If Bob does not have competent and reliable scientific evidence, he may find himself at the butt of enforcement action by FTC as well as FDA, and, sued by private plaintiffs as well.

Overall, Bob will need legal advice by FDA lawyers experienced with medical device regulation, to properly assess what he has.

One thing is for sure: unless Bob nefariously beams his quantum device so that regulators will say, “these droids are not worth your trouble,” he’ll be on FDA’s radar – it’s no surprise that the Agency has Internet access too, and can easily find Bob’s website and all the claims he makes about his consumer product. With radar ubiquitous, flying under is no longer an option. (See [FDA exerts authority over medical devices with genomics](#)).

Also, if Bob wants to have a realistic **exit strategy**, he should pay close attention to regulatory strategy, compliance, and documentation. **M&A due diligence** will uncover any holes in Bob’s FDA legal strategy.

Our FDA lawyers have counseled ventures and entrepreneurs like Bob as to their **medical device**, FDA obligations. Particularly given our interest in complementary and alternative medical therapies and holistic health, we’ve been interested in FDA legal issues long before FDA issued its guidance on general wellness products. [Connect with us](#) if you want to assess whether your product is a regulated medical device.



Contact our [healthcare law](#) and [FDA attorneys](#) for legal advice relevant to your healthcare venture.