



What a Difference a Claim Can Make: FDA Issues a Warning Letter for Unlawful Medical Device Promotion

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Much has been written, including by us, about the Food and Drug Administration's enforcement approach (or lack thereof) concerning off-label promotion. However, FDA has not curled itself up into a ball, abdicating its authority to proceed against unlawful promotion. In the medical device realm, manufacturers of devices that require 510(k) premarket notification submissions must take care to ensure that claims remain within the bounds of the product's regulatory classification. A recent Warning Letter issued to a medical device company illustrates this point.¹

In the Warning Letter issued by a district office, FDA reviewed promotional materials and the company's website during an inspection. FDA recognized that similar dermatological devices, used for dermabrasion, were exempt from the 510(k) notification requirement. However, this product worked differently, by creating small puncture wounds in the skin, and raised "different questions of safety and effectiveness." The device was not approved or cleared for marketing, but a testimonial video on the company's website promoted the product as "FDA Approved." As a result, the device was deemed adulterated (*i.e.*, no Premarket Approval Application(PMA)) and misbranded (*i.e.*, no 510(k) premarket notification clearance or pending PMA and claims of "FDA Approved").

AGG Observations

1. FDA reserves the right to take enforcement action against unlawful promotion.
2. The case did not involve off-label promotion. Instead, the focus here was on the lack of marketing authorization approval or clearance for the product itself.
3. Labeling claims and technology can change a medical device's regulatory classification from 510(k)-exempt to a device that requires authorization. Therefore, device companies planning to market products that are comparable to 510(k)-exempt devices should review carefully any changes or differences and evaluate any regulatory classification implications.
4. FDA may be more likely to take enforcement action when it sees a potential safety issue raised by the unlawful sale and promotion of a device, as was present in this case.
5. Claims of "FDA Approved" should be limited to cases in which the agency has granted a true stamp of approval, such as with a PMA device. A claim of "FDA Approved" for a 510(k) device, much less for a 510(k)-exempt device, is misleading and a prohibited act.

¹ The Warning Letter can be accessed at www.fda.gov/iceci/enforcementactions/warningletters/2016/ucm520649.htm.

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