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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, Maryland 20852

Comments of the Patient, Consumer, and Public Health Coalition
on
Reclassification of External Counter-Pulsating Devices for Treatment of Chronic Stable Angina and Effective Date of Requirement for Premarket Approval for External Counter-Pulsating Devices for Other Specified Intended Uses

Docket No. FDA-2013-N-0487

We are writing as members of the Patient, Consumer, and Public Health Coalition to express our concerns about the proposed down-classification from Class III to Class II of External Counter-Pulsating (ECP) devices for treatment of chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularization. We strongly support the proposed PMA for other indications for the same ECP devices. Our coalition includes consumer groups, patient groups, public health experts, medical professionals, and scientists who are dedicated to ensuring that all medical products sold in the U.S. are safe and effective. We enthusiastically support the FDA's mission to protect public health, and recognize that the appropriate regulation of implanted medical devices is essential to ensuring the safest and most effective medical devices for patients across the country.

Since the law specifies that high-risk devices are considered Class III, we see no justification for down-classifying this obviously high-risk device used for the high-risk indication of chronic stable angina, and all other indications. We believe that high-risk cardiac devices should remain Class III devices and be subjected to pre-market approval (PMA) because they are life-supporting and life-sustaining. When they aren't held to the higher standards of PMA, we lose 4 important safeguards:

1. Proof of safety and efficacy based on short-term clinical trials

2. FDA's authority to require post-market, long-term clinical trial safety data as a condition of approval

3. FDA's authority to inspect the manufacturing facility prior to approval

4. FDA authority to rescind approval if the device is later found to be unsafe

The law requires objective, consistent categories for determining whether a device is Class III or Class II, but the proposed division of the same high-risk devices into Class III and Class II is based on subjective judgments regarding previous data for different indications, rather than the risks involved when a new device is designed and manufactured for those indications. Moreover, having two different classifications for the same device, based on different indications, does not provide adequate safeguards for patients, or sufficient evidence-based guidelines for physicians. Instead, it provides an incentive for companies to use the easier approval pathway, the 510(k) process rather than the PMA pathway, knowing that physicians can use the implant off label for any indication that they choose.

If ECPs are downclassified to Class II for any indication, physicians and patients will lack the well-designed clinical trials and pre-market inspections to help ensure that these life-saving and life-sustaining devices are safe and effective in the short-term. The lack of a PMA will also result in years of delay before the devices are subject to inspections or post-market clinical trials, since under current law, the FDA can't require post-market studies as a condition of approval for any devices cleared through the 510(k) process. And, if anything goes wrong, FDA can't rescind approval for a device cleared through the 510(k) process. Approval through the PMA process could occur based on short-term clinical trials that indicate new devices are safe and effective and FDA could require necessary longer-term post-market studies as a condition of approval. FDA can't do that for ECPs cleared as lower-risk Class II devices through the 510(k) process.

The lack of efficacy data is especially important since there are numerous serious health risks for ECPs, as noted in the Federal Register notice: cardiac arrhythmias from excessive electrical leakage current, trauma or irritation to the limb caused by improper mechanical design, and improper timing or failure to synchronize the device with the appropriate phase of the cardiac cycle, which may result in ineffective cardiac assistance by the device, which can be fatal.

A down classification from Class III to Class II, and the resulting 510(k) clearance process, would allow a manufacturer to use less rigorous reviews to clear its device such as bench and biocompatibility tests. Special controls would not provide the high-quality data demonstrating safety and effectiveness that are needed for the wide variety of indications that these devices would be used for (and are already used for).

It is not possible for MAUDE reports to establish the safety profiles of these devices, because the patients are in such poor health that it is not surprising when a patient dies. Moreover, MAUDE reports are voluntary and usually underreport the occurrence of adverse events, especially of critically ill patients. Nevertheless, deaths and severe adverse reactions associated with these devices have been reported to the FDA. MAUDE reports can be used to eventually identify risks associated with a device, as those reports suggest, but do not provide an accurate assessment of the prevalence of each risk. The only way to ensure long-term safety data for these devices is to keep them at Class III and require long-term post-market safety studies.

As a Class III device, the FDA should require controlled clinical studies that directly compare ECPs for any indication with alternative treatments. Currently available clinical evidence does not prove safety and effectiveness for these devices for any indication. Special controls are not enough to ensure safety and effectiveness. The goal of a PMA is to determine whether a new medical device is safe and effective, while a 510(k) is based on whether the device is substantially equivalent to a moderate risk device that is already on the market. New ECPs, regardless of the specific indication, will be high-risk devices used in high-risk situations, and may be made from different materials, to other specifications, and by other manufacturers than ECPs currently on the market. Without a PMA, ECPs will not be adequately tested to make sure they have benefits that outweigh the risks for seriously ill patients.

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