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Food and Drug Administration
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Rockville, MD 20852

Comments of members of the Patient, Consumer, and Public Health Coalition on the proposed order to reclassify External Pacemaker Pulse Generator devices and Pacing System Analyzers
Docket No. FDA-2011-N-0650

As members of the Patient, Consumer, and Public Health Coalition, we strongly oppose the down-classification of External Pacemaker Pulse Generator (EPPG) devices and Pacing System Analyzers (PSAs) from Class III to Class II. EPPGs are clearly life-sustaining devices and they should remain in Class III and be reviewed by the more rigorous Premarket Approval (PMA) process, which will better ensure that the devices are safe and effective.

The Cardiovascular Devices Panel stated on March 9, 1979 that these devices should be classified into Class III because the device "provided temporary life-support and that certain kinds of failures could cause this device to emit inappropriate electrical signals, which could cause cardiac irregularities and death."[1] This statement is as accurate today as it was then, as one of the uses for these devices listed in the 2014 FDA Federal Register notice is as "a temporary substitute for the heart's intrinsic pacing system until a permanent pacemaker can be implanted."[2]

One of the predictable tragedies if this life-saving device malfunctions would be death. A review of the Manufacturer and User Facility Device Experience (MAUDE) database for the last five years (1/01/2010 through 11/30/2014) shows reports of 25 deaths associated with EPPG devices (product code DTE), 264 reports of injuries, and more than 3,500 malfunctions.[3] The FDA proposed order states that "The low frequency of serious adverse events" reported in the MAUDE database supports "the reclassification of these devices to class II."[2] We don't consider 25 deaths, 264 injuries, and more than 3,500 malfunctions a "low frequency" and point out that other devices have been restricted or recalled for much lower rates of reported serious adverse reactions. The FDA's Total Product Life Cycle (TPLC) database is consistent with the high MAUDE numbers we found. TPLC data shows 3,235 problems reported for EPPG devices in the last five years.[4] Unfortunately, as the FDA knows well, adverse events are almost always greatly under-reported, especially when problems have not been widely reported in the media.

While the FDA states in the 2014 Federal Register notice that they believe new information since the 1979 designation warrants reclassification of these devices into Class II with special controls, the recent data from the MAUDE and TPLC databases irrefutably contradicts that proposal.

The 2011 Federal Register notice stated that these devices pose "risks to health," including a failure of the electronic circuitry, which can cause failure to pace the patient's heart; improper pacing leading to high rate-electric failure, which can lead to arrhythmias or unwanted stimulation; and micro/macro shocks resulting in an arrhythmia or cardiac tissue damage.[1] The 2014 Federal Register notice adds an additional risk of "misdiagnosis," which can result in the physician prescribing "a course of treatment that places the patient at risk unnecessarily."[2] The above-mentioned adverse events reported and these newly identified risks to health suggest that EPPG devices should stay in Class III.

Several risks associated with these devices cannot be adequately mitigated by Class II with special controls. For example, "Failure to pace" is listed as one of the risks associated with these devices, which can be caused by "failure of mechanical/electrical components of the device."[2] Non-clinical performance testing cannot prevent malfunctions of individual devices. Instead, manufacturing inspections, a key feature of the PMA process, are absolutely essential to ensure that these devices are properly manufactured. For these reasons, Class II with special controls for EPPG devices do not provide reasonable assurance of their safety and effectiveness.

Regarding Pacing System Analyzers (PSA), we oppose the down-classification of the device from Class III device to Class II because for the six identified risks of the device (including "Micro/Macro Shock"[2]), the FDA relies on labeling to mitigate the risks. We strongly doubt that

labeling will adequately reduce risks since the preponderance of evidence indicates that health care providers often do not read or follow labeling instructions.

Conclusion

In January 2012, members of the Patient, Consumer, and Public Health Coalition submitted comments opposing the down-classification of EPPG devices. The FDA stated that in 2012 it received the following comments on the proposed reclassification: EPPG devices should stay in Class III, that the reclassification was "not adequately supported by new publicly valid scientific evidence" and that the performance standards (special controls) "are insufficient."[2] Those comments are still valid today. The FDA has not provided any scientific evidence to contradict them.

At a September 11, 2013 Advisory Committee meeting, one of our coalition partners, the National Research Center for Women & Families (which has since changed its name to the National Center for Health Research) spoke against the down-classification.

In conclusion, after reviewing the regulatory history, adverse event reporting, and risks associated with these devices, we strongly oppose down-classifying EPPG device to Class II with special controls. The devices should remain in Class III. This designation is needed to assure physicians and their patients that patients will not be harmed by these devices when their lives may depend on them. We also strongly oppose the down-classification of PSAs, in that case because the special controls rely heavily on labeling to mitigate risks, and there is no evidence that would be sufficient to protect the health of patients.

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Center for Science and Democracy at the Union of Concerned Scientists
Women Advocating Reproductive Safety
WomenHeart: The National Coalition for Women with Heart Disease.

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[1] Federal Register Volume 76 (October 17, 2011). Proposed rule: Cardiovascular Devices; Reclassification of External Pacemaker Pulse Generator Devices [Docket No. FDA-2011-N-0650]

[2] Federal Register Volume 79 (September 15, 2014). Proposed order: Cardiovascular Devices; Reclassification of External Pacemaker Pulse Generator Devices; Reclassification of Pacing System Analyzers [Docket No. FDA-2011-N-0650].

[3] Food and Drug Administration (accessed December 12, 2014). Manufacturer and User Facility Device Experience (MAUDE) database. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

[4] Food and Drug Administration (accessed December 12, 2014). Total Product Life Cycle for product code DTE (external pacemaker pulse generator devices). http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?ID=742&min_report_year=2010