4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA-2012-N-1173]

Cardiovascular Devices; Reclassification of External Cardiac Compressor; Reclassification of Cardiopulmonary Resuscitation Aids

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify external cardiac compressors (ECC) (under FDA product code DRM), a preamendments class III device, into class II (special controls). FDA is also creating a separate classification regulation for a subgroup of devices previously included within this classification regulation, to be called cardiopulmonary resuscitation (CPR) aids, and reclassifying these devices from class III to class II for CPR aids with feedback and to class I for CPR aids without feedback.

DATES: This order is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Hina Pinto, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 1652, Silver Spring, MD 20993, 301-796-6351, hina.pinto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background--Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (Pub. L. 101-629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), the Medical Devices Technical Corrections Act (Pub. L. 108-214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment by interested persons, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II, or

FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A preamendments device that has been classified into class III and devices found substantially equivalent by means of premarket notification (510(k)) procedures to such a preamendments device or to a device within that type (both the preamendments and substantially equivalent devices are referred to as preamendments class III devices) may be marketed without submission of a premarket approval application (PMA) until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval or until the device is subsequently reclassified into class I or class II.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the mechanism for reclassifying a device from rulemaking to an administrative order.

Section 513(e) of the FD&C Act provides that FDA may, by administrative order, reclassify a device based upon "new information." FDA can initiate a reclassification under section 513(e) or an interested person may petition FDA to reclassify a preamendments device. The term "new information," as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., Holland-Rantos Co. v. U.S. Dep't of Health, Educ. & Welfare, 587 F.2d 1173,

1174 n.1 (D.C. Cir. 1978); Upjohn Co. v. Finch, 422 F.2d 944 (6th Cir. 1970); Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see Bell, 366 F.2d at 181; Ethicon, Inc. v. FDA, 762 F. Supp. 382, 388-91 (D.D.C. 1991)), or in light of changes in "medical science" (Upjohn, 422 F.2d at 951). Whether data before the Agency are old or new data, the "new information" to support reclassification under section 513(e) must be "valid scientific evidence," as defined in section 513(a)(3) of the FD&C Act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, e.g., Gen. Med. Co. v. FDA, 770 F.2d 214 (D.C. Cir. 1985); Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the "valid scientific evidence" upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).)

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final reclassification order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the Federal Register; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket. FDA published a proposed order to reclassify this device in the Federal Register of January 8, 2013 (78 FR 1162). FDA has held a meeting of a device classification panel described in section 513(b) of the FD&C Act with respect to ECC devices, including CPR aids, and therefore, has met this requirement under section 513(e)(1) of

the FD&C Act. As explained further in section III, a meeting of a device classification panel (the Panel) described in section 513(b) of the FD&C Act took place on September 11, 2013, to discuss whether ECC devices, including CPR aids, should be reclassified or remain in class III. The Panel recommended that ECC and CPR aid devices with feedback be reclassified into class II because there was sufficient information to establish special controls to provide a reasonable assurance of safety and effectiveness. The Panel further recommended that CPR aid devices without feedback be reclassified into class I because general controls are sufficient to provide a reasonable assurance of safety and effectiveness. FDA received and has considered four comments on the proposed order as discussed in section II.

II. Public Comments in Response to the Proposed Order

In response to the January 8, 2013, proposed order to reclassify external cardiac compressors (including CPR aid devices), FDA received four comments. Two comments submitted were supportive of the proposed reclassification of the devices, citing, among other things, their safe history of use and the need for such devices in situations with inadequate access to professionally trained rescuers.

(Comment 1) One comment disagreed with FDA's proposal to reclassify ECC devices and sought a proposed order confirming their status as class III devices and requiring PMAs with data from well-controlled clinical trials to ensure that these devices are safe and effective. The comment stated that the life-sustaining nature of the device along with equivocal existing clinical evidence, including data indicating that use of ECC may result in neurological outcomes more severe than manual CPR, would support keeping the device in class III. The comment stated that classification of ECCs should be reviewed by a device classification panel. The comment further suggested that the risks to health identified in the proposed order should include death and

neurological damage, and that there are existing data that use of the ECC device or device malfunction can delay the start of compressions and that professional first-responders often use the device improperly.

(Response) FDA disagrees with the comment. FDA acknowledges that the data on the use of ECC devices as a replacement to effective manual CPR are equivocal; however, the proposed order recommended reclassification of the device as an adjunct to manual CPR. In this final order, FDA has further refined the identification for the device in 21 CFR 870.5200 to include "as an adjunct to manual cardiopulmonary resuscitation (CPR) when effective manual CPR is not possible (e.g., during patient transport, extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient EMS personnel are available to provide effective CPR)." FDA is only reclassifying into class II the ECC devices indicated for use when effective manual CPR compressions cannot otherwise be provided by the rescuer. In this final order, FDA has further revised the device identification and the labeling special controls (see section IV) to clarify this intended use.

It is well-established in the clinical community that CPR, including effective compressions, is critical to improve the chances of survival for a victim of sudden cardiac arrest (Ref. 1). In such circumstances when effective manual CPR compressions cannot be provided by the rescuer, use of an ECC device that has been demonstrated to provide compressions consistent with the American Heart Association's (AHA) "Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" is warranted (Ref. 1). Although controlled clinical trials for adjunctive use might be difficult to conduct because denying use of an ECC device on patients in the "control" arm could decrease their chance for survival, it is well established that chest compressions are crucial to maintaining perfusion and that compressions of

adequate rate and depth are necessary to increase the probability of survival in victims of sudden cardiac arrest (Ref. 1). As such, FDA believes that these devices, when indicated for use as an adjunct to manual CPR during patient transport or for use in situations where fatigue of or inaccessibility to emergency medical personnel may otherwise prevent adequate chest compressions, can be regulated as class II devices. These devices should not be used as a replacement for manual CPR.

FDA presented a modified ECC device identification and the available scientific evidence to a device classification panel that reached consensus in support of FDA's proposal for reclassification (see section III). FDA also presented the risks to health to the Panel, and there was consensus support by the Panel of the risks as originally identified.

(Comment 2) This comment also states that FDA failed to properly consider death or neurological injury as a health risk associated with these devices. However, as discussed in section III, death and neurological damage are outcomes already covered by the identified risks of "ineffective compressions."

(Response) FDA's presentation to the Panel also included a review of adverse events. This review did not reveal a significant number of adverse events associated with device malfunction or improper use, given the usage of these devices over more than a decade (e.g., 88 adverse event reports over a 12-year period, with 33 of the 88 malfunctions occurring in 1 year--2012--which can be attributed to an increase in reported problems for one particular device that eventually resulted in a recall). Additionally, these issues are also adequately addressed with the implementation of special controls related to performance data, labeling on appropriate use, and general controls, including good manufacturing practices. The Panel also reached consensus in support of the special controls, and FDA has modified the special controls in response to certain

concerns expressed by the Panel, including concerns related to potential for use of the ECC device to delay CPR (see section III).

(Comment 3) One comment suggested that CPR aid devices should be identified separately from ECC devices, and that CPR aid devices that provide feedback solely on compression should be defined separately from other CPR aid devices that provide feedback on additional CPR parameters, such as ventilation. The comment further suggested that CPR aid devices should be made widely available (e.g., "over-the-counter") and are low-risk devices that should be exempt from premarket notification (510(k)). The comment noted that the risks to health described in the proposed order as well as the proposed special controls could instead be covered by general controls, including design controls under 21 CFR part 820, and hence classification of these devices into class I was appropriate.

(Response) FDA agrees, in part, with the comment. FDA agrees that CPR aid devices are distinct in intended use and technology when compared to devices that automatically deliver compressions. In this final order, FDA has separated CPR aid devices into a separate classification regulation, 21 CFR 870.5210 (see section VI). FDA also agrees that availability of these devices over-the-counter is appropriate in certain instances when the devices are adequately designed and provided with adequate labeling on appropriate use. As discussed in this document, FDA has modified the criteria for exemption of these devices from premarket notification, and such exemption is no longer tied to prescription use as compared to over-the-counter use.

FDA disagrees, in part, with the comment related to the classification of the CPR aid devices. Although, FDA agrees that the risks associated with CPR aid devices without feedback can be adequately mitigated with general controls, FDA has determined that CPR aid devices

with feedback require special controls. FDA did consider whether it was more appropriate to evaluate the technology contained within CPR aid devices and consider appropriate regulatory controls based on technological characteristics, as opposed to prescription-use and compliance with CPR guidelines as was originally proposed. FDA determined that based on technological complexity, some CPR aid devices could be appropriately regulated in class I (general controls) and class II (special controls). CPR aid devices can be appropriately regulated as follows: (1) CPR aid devices without feedback are reclassified into class I, (2) CPR aid devices with feedback, but without software are reclassified into class II, exempt from submission of a 510(k), and (3) CPR aid devices with feedback with software are reclassified into class II (special controls), not exempt from 510(k). Further, FDA notes that design controls under 21 CFR 820.30 would apply to all CPR aid devices with software.

This final order, therefore, now divides CPR aid devices into those without feedback (class I) or with feedback (class II). This approach was presented to and supported by the Panel (see section III). CPR aid devices that do not provide feedback (e.g., hand positioning aids and "metronome" devices that provide sounds to prompt the rescuer to deliver compressions at a rate consistent with CPR guidelines) can be regulated in class I, subject to the general controls and generally exempt from premarket notification (subject to the limitations of exemption contained in § 870.9 (21 CFR 870.9)). FDA continues to believe that CPR aid devices that do provide feedback to the rescuer (e.g., devices that sit on the patient's chest, underneath the hands of the rescuer, to provide feedback on compression rate/depth/etc., or devices that provide prompts to the rescuer on appropriate CPR sequence) require special controls, in combination with general controls, to provide a reasonable assurance of safety and effectiveness. FDA acknowledges that some of the specified performance testing and other special controls requirements will be

managed as part of a manufacturer's design control process; however, FDA disagrees that the general requirements to conform to design controls requirements under 21 CFR 820.30 are sufficient to ensure that manufacturers will perform the tests and other requirements that are necessary as specifically identified in the special controls.

FDA further determined that due to their simple and well-understood technological characteristics, exemption from premarket notification (510(k)) is appropriate for mechanical or electro-mechanical CPR aid devices that provide feedback (e.g., devices that utilize bladders and pressure gauges to provide feedback on compression depth), when such devices comply with the special controls and subject to the limitations of exemption contained in § 870.9. However, devices that contain software have complex and evolving levels of visual and audio feedback to users, warranting continued review under the 510(k) process.

III. Deliberations of the Panel

In Session I on September 11, 2013, the Circulatory System Devices Panel (the Panel) of the Medical Devices Advisory Committee considered the proposed reclassification of ECC devices (Ref. 2). The Panel was asked to provide input on the risks to health, safety, and effectiveness of ECC devices and CPR aid devices. The Panel was also asked to consider FDA's proposed premarket regulatory classification strategy for ECC and CPR aid devices, which, for CPR aid devices in particular, had been modified based on public comments received on the proposed order for ECC devices (see FDA's Panel Executive Summary, Ref. 2). The regulatory strategy presented to the Panel included: (1) Reclassification for ECC devices from class III to class II (special controls); (2) reclassification of CPR aid devices without feedback to class I (general controls), with over-the-counter access appropriate if the device is labeled for professionally trained rescuers; and (3) reclassification of CPR aid devices with feedback to class

II (special controls), with over-the-counter access appropriate if human factors testing demonstrates proper use by the intended user identified in the labeling (professionally trained and/or untrained lay rescuers).

The Panel reached consensus in supporting the aforementioned classification strategy for CPR aid devices. There was significant panel deliberation on reclassification of the automated ECC devices that deliver compressions. The Panel expressed concern regarding the limited available clinical evidence for these devices. Based on the definition of valid scientific evidence in § 860.7(c)(2), which allows for "reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is a reasonable assurance of the safety and effectiveness of a device under its conditions of use" and the wide clinical knowledge base supporting that effective CPR (including compressions) optimize the chance for survival of victims of cardiac arrest, the Panel consensus was that it was appropriate to reclassify these devices for adjunctive use (e.g., in situations where a rescuer cannot provide effective manual compressions). The Panel acknowledged that there is insufficient evidence to conclude that ECC devices are as effective as manual CPR.

As discussed at the Panel meeting, FDA has identified the public health benefits in using ECC devices (Ref. 2). Automated ECCs are used by emergency medical personnel to automate chest compressions during CPR. These devices are typically used in situations where extended CPR is required, such as during patient transport or when there are an inadequate number of trained personnel during extended CPR. FDA believes that these devices, when indicated for use as an adjunct to manual CPR during patient transport or for use in situations where fatigue of or inaccessibility to emergency medical personnel may otherwise prevent adequate chest

compressions, will serve a public health benefit. In the absence of effective chest compressions, death is a likely outcome.

CPR aid devices also have public health benefits because these devices are used to remind emergency medical personnel of appropriate CPR steps and technique and to provide feedback on the rate and depth of compressions (Ref. 2). Specifically, these devices are intended to assist the rescuer in providing consistent and effective/optimal CPR, and can include instruction, rate, and/or breathing prompts, and real-time feedback through the duration of CPR and in accordance with current accepted CPR guidelines. The AHA guidelines on cardiopulmonary resuscitation and emergency cardiovascular care state that "real-time CPR prompting and feedback technology such as visual and auditory prompting devices can improve the quality of CPR" (Ref. 1). CPR aid devices are intended to encourage the rescuer to perform consistent and optimal CPR over the duration of needed therapy.

FDA also presented the risks to health to the Panel, and the Panel reached consensus in supporting the risks as originally identified with the following comments: (1) The risks identified for CPR aid devices should also include the same risks as identified for the ECC devices because a CPR aid device that provides incorrect feedback can result in similar risks as the ECC devices, and (2) death and neurologic injury are not specifically identified in the ECC risks. FDA considered the Panel's input related to the risks of the device and determined that the originally proposed risks of the devices are appropriate. The risks to health are those risks directly associated with use of the device. The CPR aid device cannot directly cause tissue damage, bone breakage, etc. and these risks are a consequence of the application of CPR by a rescuer. Moreoever, since "ineffective compressions" could result in neurological damage

and/or death, these risks are adequately covered by the identified risk of "ineffective compressions."

The Panel also made recommendations to FDA regarding additional special controls for ECC and CPR aid devices including: (1) Disclosure of limitations on patient size and/or use population, (2) controls over the time necessary to deploy the device, and (3) reinforcing that the ECC device is for adjunctive use. FDA agrees with the special control recommendations for ECC devices and has revised the special controls accordingly; for CPR aid devices, FDA does not believe controls are necessary during the time needed to deploy the device since use of these devices would not result in a significant delay in administering CPR.

After considering input from the Panel, FDA has determined that the risks to health identified for ECC and CPR aid devices (with and without feedback) can be adequately mitigated by the special controls as outlined in tables 1 to 3.

Table 1.--Risks to Health and Mitigation Measures for ECC Devices

Identified Risk	Mitigation Measures
Cardiac arrhythmias or electrical shock	• Electrical Safety and Electromagnetic Compatibility Testing (e.g., ISO 60601-1 and ISO 60601-1-2) • Labeling
Tissue/organ damage	• Performance testing, including bench testing • Software verification/validation/hazards analysis • Human factors testing and analysis • Labeling • Training
Bone breakage (ribs, sternum)	• Performance testing, including bench testing • Software verification/validation/hazards analysis • Human factors testing and analysis • Labeling • Training
Inadequate blood flow	• Performance testing, including bench testing • Software verification/validation/hazards analysis • Human factors testing and analysis • Labeling • Training
Adverse skin reactions	• Assessment/use of biocompatible materials

Table 2.--Risks to Health and Mitigation Measures for CPR Aid Devices With Feedback

Identified Risk	Mitigation Measures
Suboptimal CPR delivery	• Performance testing • For devices that incorporate electrical components, electrical safety and electromagnetic compatibility testing; • For devices containing software, software verification, validation, and hazard; • Human factors testing and analysis; • Labeling must include clinical training, if needed.
Adverse skin reactions	• Assessment/use of biocompatible materials

Table 3.--Risks to Health and Mitigation Measures for CPR Aid Devices Without Feedback

Identified Risk	Mitigation Measures
Suboptimal CPR delivery	• General Controls o Labeling: Intended for use by professionally trained rescuers o Quality system regulation requirements, including design controls for devices that include software
Adverse skin reactions	• Assessment/use of biocompatible materials[1]

[1] Given the benefit/risk profile, this risk can be adequately mitigated in this patient population by general controls.

IV. The Final Order

Under section 513(e) of the FD&C Act, FDA is adopting its findings, in part, as published in the preamble to the proposed order (78 FR 1162, January 8, 2013). FDA has made revisions in this final order in response to the comments received (see section II) and the deliberations of the Panel (see section III). As published in the proposed order, FDA is issuing this final order to reclassify ECC (under FDA product code DRM) from class III to class II and establish special controls by revising part 870 (21 CFR 870.5200). The identification for 21 CFR 870.5200 has been revised to specify that these are prescription devices and to clarify that these devices are reclassified only for adjunctive use by changing the identification to read "…

when effective manual CPR is not possible (e.g., during patient transport or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient EMS personnel are available to provide effective CPR)."

For clarity, in this final order, FDA has created a separate classification regulation for CPR aid devices, 21 CFR 870.5210, instead of continuing to include these devices within the ECC classification regulation as was originally proposed and how the devices were originally cleared for marketing authorization. In making this decision, FDA considered a comment received on the proposed order that supported creating a separate identity for CPR aid devices because their intended uses and technological characteristics are distinct from ECC devices. Additionally, the creation of a separate classification regulation for CPR aid devices allows for further clarification of the exemption from the premarket notification procedures for certain devices. The new classification regulation for CPR aid devices in this final order includes the same special controls that were included in the 2013 proposed order; however, FDA has divided the CPR aid identification into devices that provide feedback to the rescuer and those that do not. Devices that do not provide feedback have been reclassified into class I, based upon the ability of general controls to sufficiently mitigate the risks to health and demonstrate a reasonable assurance of safety and effectiveness of these devices, whereas devices that do provide feedback are reclassified into class II as originally proposed, based upon the additional need for special controls, in combination with general controls, to sufficiently mitigate the risks to health and demonstrate a reasonable assurance of safety and effectiveness of these devices.

In response to the input of the Panel, FDA also made refinements to the proposed special controls. FDA added special controls requirements for automated ECC devices, including performance testing of the time necessary to deploy the device and additional labeling

requirements that include: (1) Prominent display of adjunctive-only use of the device, (2) labeling of the expected deployment time, and (3) labeling limitations on patient population/size (e.g., adult, pediatric, infant) for use of the device. FDA also added the labeling requirement regarding limitations on patient population/size for the CPR aid devices and modified the language for the human factors special controls to read: "Human factors testing and analysis must validate that the device design and labeling are sufficient for the intended user."

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the devices. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of ECC devices, and therefore, this device type is not exempt from premarket notification requirements. However, FDA has determined that premarket notification is not necessary for some class II CPR aid devices. FDA modified the criteria for exemption from section 510(k) for CPR aid devices with feedback from the originally proposed "if it is a prescription use device that provides feedback to the rescuer consistent with the current AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science in compliance" to "if it does not contain software (e.g., is mechanical or electro-mechanical)."

Following the effective date of this final order, firms marketing an ECC device or CPR aid device with feedback must comply with the applicable mitigation measures set forth in the codified special controls (see section VII). Manufacturers of ECC devices and CPR aid devices with feedback that have not been legally marketed prior to the effective date of the final order, or models (if any) that have been legally marketed but are required to submit a new 510(k) under 21

CFR 807.81(a)(3) because the device is about to be significantly changed or modified, must obtain 510(k) clearance and demonstrate compliance with the special controls included in the final order, before marketing the new or changed device.

V. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final order refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814, subpart B, are approved under OMB control number 0910-0231; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

VII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore,

under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this final order, we are revoking the requirements in 21 CFR 870.5200 related to the classification of ECCs as class III devices and codifying the reclassification of ECCs into class II (special controls) and also codifying in 21 CFR 870.5210 the reclassification of CPR Aid devices with feedback into class II (special controls) and CPR Aid devices without feedback into class I (general controls).

VIII. References

The following references are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. Field, J.M., M.F. Hazinski, M.R. Sayre, et al., "Part 1: Executive Summary: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care," Circulation, 122:S640-S656, 2010, available at: http://circ.ahajournals.org/content/122/18_suppl_3.toc.

2. The Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting (September 11-12, 2013) transcript, executive summary, and other meeting materials are available on FDA's Web site at http://www.fda.gov/advisorycommittees/calendar/ucm364767.htm.

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

PART 870--CARDIOVASCULAR DEVICES

1. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Revise § 870.5200 to read as follows:

§ 870.5200 External cardiac compressor.

(a) Identification. An external cardiac compressor is an externally applied prescription device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest. External cardiac compressor devices are used as an adjunct to manual cardiopulmonary resuscitation (CPR) when effective manual CPR is not possible (e.g., during patient transport or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient EMS personnel are available to provide effective CPR).

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Nonclinical performance testing under simulated physiological conditions must demonstrate the reliability of the delivery of specific compression depth and rate over the intended duration of use.

(2) Labeling must include the following:

(i) The clinical training necessary for the safe use of this device;

(ii) Adjunctive use only indication prominently displayed on labels physically placed on the device and in any device manuals or other labeling;

(iii) Information on the patient population for which the device has been demonstrated to be effective (including patient size and/or age limitations, e.g., adult, pediatric and/or infant); and

(iv) Information on the time necessary to deploy the device as demonstrated in the performance testing.

(3) For devices that incorporate electrical components, appropriate analysis and testing must demonstrate that the device is electrically safe and electromagnetically compatible in its intended use environment.

(4) Human factors testing and analysis must validate that the device design and labeling are sufficient for effective use by the intended user, including an evaluation for the time necessary to deploy the device.

(5) For devices containing software, software verification, validation, and hazard analysis must be performed.

(6) Components of the device that come into human contact must be demonstrated to be biocompatible.

3. Add § 870.5210 to subpart F to read as follows:

§ 870.5210 Cardiopulmonary resuscitation (CPR) aid.

(a) CPR aid without feedback--(1) Identification. A CPR aid without feedback is a device that performs a simple function such as proper hand placement and/or simple prompting for rate and/or timing of compressions/breathing for the professionally trained rescuer, but offers no feedback related to the quality of the CPR being provided. These devices are intended for use by persons professionally trained in CPR to assure proper use and the delivery of optimal CPR to the victim.

(2) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

(b) CPR aid with feedback--(1) Identification. A CPR Aid device with feedback is a device that provides real-time feedback to the rescuer regarding the quality of CPR being delivered to the victim, and provides either audio and/or visual information to encourage the rescuer to continue the consistent application of effective manual CPR in accordance with current accepted CPR guidelines (to include, but not be limited to, parameters such as compression rate, compression depth, ventilation, recoil, instruction for one or multiple rescuers, etc.). These devices may also perform a coaching function to aid rescuers in the sequence of steps necessary to perform effective CPR on a victim.

(2) Classification. Class II (special controls). The special controls for this device are:

(i) Nonclinical performance testing under simulated physiological or use conditions must demonstrate the accuracy and reliability of the feedback to the user on specific compression rate, depth and/or respiration over the intended duration, and environment of use.

(ii) Labeling must include the clinical training, if needed, for the safe use of this device and information on the patient population for which the device has been demonstrated to be effective (including patient size and/or age limitations, e.g., adult, pediatric and/or infant).

(iii) For devices that incorporate electrical components, appropriate analysis and testing must demonstrate that the device is electrically safe and electromagnetically compatible in its intended use environment.

(iv) For devices containing software, software verification, validation, and hazard analysis must be performed.

(v) Components of the device that come into human contact must be demonstrated to be biocompatible.

(vi) Human factors testing and analysis must validate that the device design and labeling are sufficient for effective use by the intended user.

(3) Premarket notification. The CPR Aid with feedback device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter if it does not contain software (e.g., is mechanical or electro-mechanical) and is in compliance with the special controls under paragraph (b)(2) of this section, subject to the limitations of exemptions in § 870.9.

Dated: May 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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