4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 884, 888, and 890

[Docket No. FDA-2019-N-2686]

Medical Devices; Exemptions From Premarket Notification: Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is publishing an order setting forth the Agency's final determination to exempt a list of class II devices from premarket notification (510(k)) requirements, subject to certain limitations. This exemption from 510(k), subject to certain limitations, is immediately in effect for the list of class II devices. The exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations. FDA is also amending the codified language for the list of class II devices to reflect this final determination. FDA is publishing this order in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

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

FOR FURTHER INFORMATION CONTACT: Jismi Johnson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1528, Silver Spring, MD 20993, 301-796-6424, Jismi.johnson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and its implementing regulations in part 807, subpart E (21 CFR part 807, subpart E), persons who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use are required to submit a 510(k) to FDA. The device may not be marketed until FDA finds it "substantially equivalent" within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

On December 13, 2016, the 21st Century Cures Act (Cures Act) (Pub. L. 114-255) was signed into law. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(2) of the FD&C Act provides that, 1 calendar day after the date of publication of the final list under section 510(m)(1)(B) of the FD&C Act,[1] FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act, upon its own initiative or a petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the *Federal Register* a notice of intent to exempt a device, or of the petition, and provide a 60-calendar-day comment period. Within 120 days of publication of such notice, FDA shall publish an order in the *Federal Register* that sets forth its final determination regarding the exemption of the device that was the subject of the notice.

[1] FDA published the final list under section 510(m)(1)(B) of the FD&C Act in the *Federal Register* of July 11, 2017 (82 FR 31976).

In the *Federal Register* of October 25, 2019 (84 FR 57445), in accordance with the amendments to section 510(m)(2) of the FD&C Act, on its own initiative, FDA issued a notice of intent to exempt the identified class II devices from premarket notification requirements under section 510(k) of the FD&C Act, subject to certain limitations. Having received no comments to the docket following a 60-day comment period, FDA is issuing this order to set forth our final determination to exempt the class II devices that were the subject of the notice. Through this action, FDA is now amending the codified language for each identified classification regulation to reflect our final determinations for these class II exemptions[2].

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, *Federal Register* notice (63 FR 3142) and subsequently in the guidance we issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff" ("Class II 510(k) Exemption Guidance"). That guidance can be obtained through the internet at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf or by sending an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the document. Please use the document number 159 to identify the guidance you are requesting.

III. Limitations on Exemptions

[2] FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

FDA has determined that premarket notification is not necessary to provide a reasonable assurance of safety and effectiveness of the class II devices listed in table 1. This determination is based, in part, on the Agency's knowledge of the device, including past experience and relevant reports or studies on device performance (as appropriate), the applicability of general and special controls, and the Agency's ability to limit an exemption.

A. General Limitations of Exemptions

FDA's exemption from premarket notification for the class II devices listed in table 1 applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type. A manufacturer of a listed device would still be required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into commercial distribution when the device meets any of the conditions described in 21 CFR 884.9, 888.9, and 890.9.

B. Partial Limitations of Exemptions

In addition to the general limitations, FDA may also partially limit an exemption from premarket notification requirements to specific devices within a listed device type when an initial Agency assessment determines that the factors laid out in the Class II 510(k) Exemption Guidance do not weigh in favor of exemption for all devices in a particular group. In such situations where a partial exemption limitation has been identified, FDA has determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for these devices. In table 1, for example, FDA is listing the exemption of the optical position/movement recording system but limits the exemption to such devices that are for prescription use only. FDA believes that premarket review (e.g., premarket notification) of an optical position/movement recording system for over-the-counter (OTC) use is necessary to

ensure that the exercises and activities led by the system are appropriate for a user's rehabilitation and to assess the measurement accuracy of the system. Additionally, a therapeutic massager to internally massage trigger points in the pelvic floor musculature would exceed the exemption limitation and would require 510(k) review if it is indicated for OTC use, lacks a quantitative feedback mechanism, or lacks a disposable covering.

IV. List of Class II Devices

In this final order, FDA is identifying the following list of class II devices that no longer require premarket notification under section 510(k) of the FD&C Act, subject to the general limitations to the exemptions found in 21 CFR 884.9, 888.9, and 890.9 and any partial exemption limitations identified in table 1.

FDA assigned new product codes to the device types that are exempt subject to the partial limitations to ensure that these devices can be separated from devices that do not fall within the partial exemption limitation under the existing product code (i.e., exempt and non-exempt devices within a device type now have distinct product codes).

Table 1--Class II Devices

21 CFR Section	Device Type	Exempt Product Code	Non-Exempt Product Code (Non-Exempt)	Partial Exemption Limitation (if applicable)
884.6120	Accessory, Assisted Reproduction	QKH	MQG	Exemption is limited to assisted reproduction laminar flow workstations.
884.6180	Media, Reproductive	QKI	MQL	Exemption is limited to phosphate-buffered saline used for washing, and short-term handling and manipulation of gametes and embryos; culture oil used as an overlay for culture media containing gametes and embryos; and water for assisted reproduction applications.
888.4505	Instruments Designed for Press-Fit Osteochondral implants	Not Applicable	QBO	Not Applicable
890.5360*	Interactive Rehabilitation Exercise Devices	QKC	LXJ	Exemption is limited to prescription (Rx) use only.

21 CFR Section	Device Type	Exempt Product Code	Non-Exempt Product Code (Non-Exempt)	Partial Exemption Limitation (if applicable)
890.5670	Massager, Therapeutic, to Internally Massage Trigger Points in the Pelvic Floor Musculature	QKD	OSD	Exemption is limited to prescription (Rx) use only devices which incorporate a quantitative feedback mechanism and a disposable covering.

* FDA is revising the name of the device type under product code LXJ from "System, Optical Position/Movement Recording" to "Interactive Rehabilitation Exercise Devices."

FDA is also revising the name of product code LXJ to further clarify the device type that this product code is intended to represent, identified with an asterisk in table 1. The device type was previously "System, Optical Position/Movement Recording." This product code also includes types of rehabilitation devices other than optical position/movement recording systems; therefore, to more accurately reflect the devices which fall within this device type (product code LXJ), the device type has been renamed "Interactive Rehabilitation Exercise Devices." The new product code, QKC, which represents the class II exempt counterpart of LXJ and reflects the partial exemption limited to prescription use, also reflects this name change.

V. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) 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

FDA concludes that this final order contains no new collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521) is not required. This final order refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in in 21 CFR part 807,

subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910-0485; and the collections of information in part 820, regarding quality system regulation, have been approved under OMB control number 0910-0073.

List of Subjects

21 CFR Parts 884, 888, and 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 884, 888, and 890 are amended as follows:

PART 884--OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for part 884 continues to read as follows:

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

2. In § 884.6120, revise paragraph (b) to read as follows:

§ 884.6120 Assisted reproduction accessories.

* * * * *

(b) *Classification*. Class II (special controls) (design specifications, labeling requirements, and clinical testing). The device, when it is a simple embryo incubator with only temperature, gas, and humidity control; a syringe pump; a collection tube warmer; a dish/plate/microscope stage warmer; a controlled-rate cryopreservation freezer; or an assisted reproduction laminar flow workstation is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

3. In § 884.6180, revise paragraph (b) to read as follows:

§ 884.6180 Reproductive media and supplements.

* * * * *

(b) *Classification*. Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing). The device, when it is phosphate-buffered saline used for washing, and short-term handling and manipulation of gametes and embryos; culture oil used as an overlay for culture media containing gametes and embryos; and water for assisted reproduction applications, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

PART 888--ORTHOPEDIC DEVICES

4. The authority citation for part 888 continues to read as follows:

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

5. Amend § 888.4505 by revising paragraph (b) introductory text to read as follows:

§ 888.4505 Orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation.

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(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 888.9. The special controls for this device are:

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PART 890--PHYSICAL MEDICINE DEVICES

6. The authority citation for part 890 continues to read as follows:

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

7. In § 890.5360, revise paragraph (b) to read as follows:

§ 890.5360 Measuring exercise equipment.

* * * * *

(b) *Classification*. Class II (special controls). The device, when it is a measuring exerciser or an interactive rehabilitation exercise device for prescription use only, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

8. Amend § 890.5670 by revising paragraph (b) introductory text to read as follows:

§ 890.5670 Internal therapeutic massager.

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(b) *Classification*. Class II (special controls). The device, when it is for prescription use only with a quantitative feedback mechanism and a disposable covering, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9. The special controls for this device are:

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Dated: July 9, 2020.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

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