



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA-2017-N-1609]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Oral Removable Palatal Space Occupying Device for Weight Management and/or Weight Loss

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is classifying the oral removable palatal space occupying device for weight management and/or weight loss into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the oral removable palatal space occupying device for weight management and/or weight loss classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on September 26, 2016.

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SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or 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 part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, also known as De Novo classification, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a

determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On July 31, 2015, Scientific Intake submitted a request for classification of the Sensor Monitored Alimentary Restriction Therapy (SMART) device under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on September 26, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 876.5981.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an oral removable palatal space occupying device for weight management and/or weight loss will need to comply with the special controls named in this final order. A De Novo classification decreases regulatory burdens. When FDA classifies a device type as class I or II via the De Novo pathway, other manufacturers do not have to submit a De Novo request or premarket approval application to market the same type of device, unless the device has a new intended use or technological characteristics that raise different questions of safety or effectiveness. Instead, manufacturers can use the less burdensome 510(k) pathway, when necessary, to market their device, and the device that was the subject of the original De Novo classification can serve as a predicate device for additional 510(k)s from other manufacturers.

The device is assigned the generic name oral removable palatal space occupying device for weight management and/or weight loss, and it is identified as a prescription device that is worn during meals to limit bite size, thereby reducing the amount of food that is consumed. The device may contain recording sensors for monitoring patient use. This classification does not include devices that are intended to treat any dental diseases or conditions.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

Table 1.--Oral Removable Palatal Space Occupying Device for Weight Management and/or Weight Loss Risks to Health and Mitigation Measures

Identified Risks	Mitigation Measures
Tooth Movement, Irritation, and Soreness of Mouth or Gums, including: <ul style="list-style-type: none"> • Improper mold making; • User error; and • Damage to material (soft edge separation) 	Non-clinical performance testing Labeling Training
Choking or gag reflex	Clinical performance testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Incorrect data interpretation, including: <ul style="list-style-type: none"> • Hardware malfunction (sensor malfunction) 	Non-clinical performance testing Labeling Training
Electrical shock and electrical interference with other devices	Non-clinical performance testing
Weight gain	Clinical performance testing Labeling

FDA believes that the special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness.

Oral removable palatal space occupying devices for weight management and/or weight loss are not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109, Prescription devices).

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), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA believes premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, is planning to exempt the device from the premarket notification requirements under section 510(m) of the FD&C Act. Once finalized, persons who intend to market this device type need

not submit a 510(k) premarket notification containing information on the oral removable palatal space occupying device for weight management and/or weight loss prior to marketing the device.

II. 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.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other 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 part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 876

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 876 is amended as follows:

PART 876--GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for part 876 continues to read as follows:

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

2. Add § 876.5981 to subpart F to read as follows:

§ 876.5981 Oral removable palatal space occupying device for weight management and/or weight loss.

(a) Identification. An oral removable palatal space occupying device for weight management and/or weight loss is a prescription device that is worn during meals to limit bite size, thereby reducing the amount of food that is consumed. The device may contain recording sensors for monitoring patient use. This classification does not include devices that are intended to treat any dental diseases or conditions

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

(1) The patient-contacting components of the device must be demonstrated to be biocompatible for its intended use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, as follows:

(i) Mechanical testing must demonstrate that the device performs as intended for the labeled use life and does not create forces that result in movement of teeth and damage to teeth.

(ii) Electrical safety and electromagnetic compatibility testing must demonstrate that the device performs as intended.

(iii) Software verification and validation must demonstrate that the device performs as intended.

(iv) Battery testing must demonstrate that the device battery performs as intended.

(3) Clinical performance testing must demonstrate the device performs as intended and must include an evaluation for choking.

(4) Device labeling must address the following:

(i) Patient labeling must state:

(A) The clinical benefit of weight management and/or weight loss as assessed by using percent total body weight loss;

(B) Treatment must be offered in combination with a behavioral modification program;

(C) Instructions on how to use the device as intended; and

(D) The use life of the device.

(ii) Physician labeling must state:

(A) The clinical benefit of weight management and/or weight loss as assessed by using percent total body weight loss;

(B) Treatment must be offered in combination with a behavioral modification program;

(C) Instructions on how to use the device as intended; and

(D) The use life of the device.

(5) Training must be provided to health professionals that includes procedures for determining a patient's oral health status, instructions for making the palatal mold, and assessment of issues with the device that may require service by the manufacturer.

Dated: July 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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