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; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final order entitled "Medical Devices; Gastroenterology-Urology Devices; Classification of the Oral Removable Palatal Space Occupying Device for Weight Management and/or Weight Loss" that appeared in the *Federal Register* of July 28, 2017. The final order was published with an incorrect statement in the preamble about whether FDA planned to exempt the device from premarket notification requirements. This document corrects that error.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*.]

FOR FURTHER INFORMATION CONTACT: Mark Antonino, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G208, Silver Spring, MD 20993-0002, 240-402-9980, mark.antonino@fda.hhs.gov.SUPPLEMENTARY INFORMATION:

In the *Federal Register* of July 28, 2017 (82 FR 35067), FDA published the final order "Medical Devices; Gastroenterology-Urology Devices; Classification of the Oral Removable Palatal Space Occupying Device for Weight Management and/or Weight Loss." The final order

published with an incorrect statement in the preamble about whether FDA planned to exempt the device from premarket notification requirements under section 510(k) of the FD&C Act.

In the *Federal Register* of July 28, 2017, (82 FR 35067), the following correction is made: On page 35069, in the first column, the first paragraph is corrected as follows:

"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 has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the oral removable palatal space occupying device for weight management and/or weight loss they intend to market."

Dated: October 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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