

considering several factors including the anticipated 2016–17 crop size, the committee's estimates of the incoming reserve funds and other income, and its anticipated expenses.

A review of historical and preliminary information pertaining to the upcoming crop year indicates that the producer price for the 2015–16 crop year was approximately \$78.00 per hundredweight of dates. Utilizing that price, the estimated crop size, and the assessment rate of \$0.05 per hundredweight, the estimated assessment revenue for the 2016–17 crop year as a percentage of total producer revenue is approximately .00064 percent.

This action decreases the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and decreasing the assessment rate reduces the burden on handlers, and may reduce the burden on producers. In addition, the committee meeting was widely publicized throughout the California date industry, and all interested persons were invited to attend the meetings and encouraged to participate in committee deliberations on all issues. Like all committee meetings, the June 22, 2016, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Industry members also discussed the various possible assessment rates, potential crop size, and estimated expenses at this meeting. Finally, interested persons are invited to submit comments on this interim rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0178, "Vegetable and Specialty Crop Marketing Orders." No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This action imposes no additional reporting or recordkeeping requirements on either small or large Riverside County, California date handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other

information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <https://www.ams.usda.gov/rules-regulations/moa/small-businesses>. Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The 2016–17 crop year begins on October 1, 2016, and the marketing order requires that the rate of assessment for each crop year apply to all assessable dates handled during such crop year; (2) the action decreases the assessment rate for assessable dates beginning with the 2016–17 crop year; (3) handlers are aware of this action which was unanimously recommended by the committee at a public meeting and is similar to other assessment rate actions issued in past years; and (4) this interim rule provides a 60-day comment period, and all comments timely received will be considered prior to finalization of this rule.

#### List of Subjects in 7 CFR Part 987

Dates, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 987 is amended as follows:

#### **PART 987—DOMESTIC DATES PRODUCED OR PACKED IN RIVERSIDE COUNTY, CALIFORNIA**

■ 1. The authority citation for 7 CFR part 987 continues to read as follows:

**Authority:** 7 U.S.C. 601–674.

■ 2. Section 987.339 is revised to read as follows:

#### **§ 987.339 Assessment rate.**

On and after October 1, 2016, an assessment rate of \$0.05 per hundredweight is established for dates produced or packed in Riverside County, California.

Dated: September 16, 2016.

**Elanor Starmer,**

*Administrator, Agricultural Marketing Service.*

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**BILLING CODE 3410–02–P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 878**

[Docket No. FDA–2016–N–2562]

#### **Medical Devices; General and Plastic Surgery Devices; Classification of the Magnetic Surgical Instrument System**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the Magnetic Surgical Instrument System 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 magnetic surgical instrument system's 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 September 21, 2016. The classification was applicable on June 13, 2016.

**FOR FURTHER INFORMATION CONTACT:** Varun Pattani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G452, Silver Spring, MD, 20993–0002, 301–796–6368, [varun.pattani@fda.hhs.gov](mailto:varun.pattani@fda.hhs.gov).

#### **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), 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, 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) of the FD&C Act, the person requests a classification under section 513(f)(2). 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 February 9, 2015, Levita Magnetics International Corp., submitted a request for classification of the Levita Magnetic Surgical System 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) of the FD&C Act. 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 June 13, 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 878.4815.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a magnetic surgical instrument system will need to comply with the special controls named in this final order. The device is assigned the generic name magnetic surgical instrument system, and it is identified as a prescription device used in laparoscopic surgical procedures consisting of several components, such as surgical instruments, and a magnetic controller. The magnetic controller is provided separately from the surgical instrument and is used outside the patient. The external magnetic controller is magnetically coupled with the internal surgical instrument(s) at the surgical site to grasp, hold, retract, mobilize, or manipulate soft tissue and organs.

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

TABLE 1—MAGNETIC SURGICAL INSTRUMENT SYSTEM RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Tissue Damage .....	In vivo Performance Testing. Human Factors Testing and Analysis. Training. Labeling.
Need for Extended or Additional Surgery: <ul style="list-style-type: none"> <li>• Inability to couple the external magnet with the internal surgical instrument</li> <li>• Inability to retrieve or maneuver device</li> <li>• Inability to visualize critical anatomical structures</li> </ul>	In vivo Performance Testing. Non-clinical Performance Testing. Human Factors Testing and Analysis. Training. Labeling.
Abdominal Wall Injury .....	In vivo Performance Testing. Human Factors Testing and Analysis. Labeling.
Electromagnetic Field Incompatibility or Interference (including ferromagnetic implants in users and patients, electrosurgical devices, etc.).	Non-clinical Performance Testing.
Adverse Tissue Reaction .....	Human Factors Testing and Analysis. Training. Labeling.
Infection .....	Biocompatibility Evaluation. Sterilization Validation. Reprocessing Validation. Shelf Life Validation. Labeling.

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

A magnetic surgical instrument system device is 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) 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 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 magnetic surgical instrument system they intend to market.

## II. 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 878

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 878 is amended as follows:

## PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

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

■ 2. Add § 878.4815 to subpart E to read as follows:

### § 878.4815 Magnetic surgical instrument system.

(a) *Identification.* A magnetic surgical instrument system is a prescription device used in laparoscopic surgical procedures consisting of several components, such as surgical instruments, and a magnetic controller. The magnetic controller is provided separately from the surgical instrument and is used outside the patient. The external magnetic controller is magnetically coupled with the internal surgical instrument(s) at the surgical site to grasp, hold, retract, mobilize, or manipulate soft tissue and organs.

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

(1) In vivo performance data must demonstrate that the device performs as intended under anticipated conditions of use. Testing must demonstrate the ability of the device to grasp, hold, retract, mobilize, or manipulate soft tissue and organs.

(2) Non-clinical performance data must demonstrate that the system performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Magnetic field strength testing characterization to identify the distances from the magnet that are safe for patients and users with ferromagnetic implants, devices, or objects.

(ii) Ability of the internal surgical instrument(s) to be coupled, de-coupled, and re-coupled with the external magnet over the external magnet use life.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components that are patient-contacting.

(5) Methods and instructions for reprocessing reusable components must be validated.

(6) Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components and device functionality over the labeled shelf life.

(7) Training must be developed and validated by human factors testing and analysis to ensure users can follow the instructions for use to allow safe use of the device.

(8) Labeling must include:

(i) Magnetic field safe zones.

(ii) Instructions for proper device use.

(iii) A screening checklist to ensure that all patients and operating staff are screened from bringing ferromagnetic implants, devices, or objects near the external magnet.

(iv) Reprocessing instructions for any reusable components.

(v) Shelf life.

(vi) Use life.

Dated: September 15, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### 24 CFR Part 5

[Docket No. FR 5863–F–02]

RIN 2506–AC40

### Equal Access in Accordance With an Individual's Gender Identity in Community Planning and Development Programs

**AGENCY:** Office of the Secretary, HUD.

**ACTION:** Final rule.

**SUMMARY:** Through this final rule, HUD ensures equal access for individuals in accordance with their gender identity in programs and shelter funded under programs administered by HUD's Office of Community Planning and Development (CPD). This rule builds upon HUD's February 2012 final rule entitled "Equal Access to Housing in HUD Programs Regardless of Sexual Orientation or Gender Identity" (2012 Equal Access Rule), which aimed to ensure that HUD's housing programs would be open to all eligible individuals and families regardless of sexual orientation, gender identity, or marital status. The 2012 Equal Access Rule, however, did not address how transgender and gender non-conforming individuals should be accommodated in temporary, emergency shelters, and other buildings and facilities used for shelter, that have physical limitations or configurations that require and that are permitted to have shared sleeping quarters or shared bathing facilities. This final rule follows HUD's November 2015 proposed rule, which addressed