SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

Country	Entity	License requirement	License review policy	Federal Register citation
	Gulf Gate Sea Cargo LLC, No. 508, Bldg P–114, Almaktoum Road, Deirah, Dubai, United Arab Emirates; *and* P.O. Box 39948, Dubai, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
	Gulf Gate Shipping Co. LLC, No. 508, Bldg P–114, Almaktoum Road, Deirah, Dubai, United Arab Emirates; *and* P.O. Box 39948, Dubai, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
*	*	*	* *	*
	Mehrdad Moeinansari, a.k.a., the following one alias: —Mehrdad Ansari. No 7101, Index Tower DIFC, Dubai, U.A.E.; *and* No 508, Sheikha Maryam Bldg., Deirah, Dubai, U.A.E. 39948.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	81 FR [INSERT FR PAGE NUMBER] 6/21/16.
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Dated: June 9, 2016.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2016–14515 Filed 6–20–16; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2016–N–1318]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Gynecologic Laparoscopic Power Morcellation Containment System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the gynecologic laparoscopic power morcellation containment 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 gynecologic laparoscopic power morcellation containment 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 June 21, 2016. The classification was applicable on April 7, 2016.

FOR FURTHER INFORMATION CONTACT: Veronica Price, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G116, Silver Spring, MD 20993–0002, 301–796–6538, *veronica.price@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) 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, 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). 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 will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On June 19, 2015, Advanced Surgical Concepts submitted a request for classification of the PneumoLiner device under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

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 April 7, 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 884.4050.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a gynecologic laparoscopic power morcellation containment system will need to comply with the special controls named in this final order.

The device is assigned the generic name gynecologic laparoscopic power morcellation containment system and is identified as a prescription device consisting of an instrument port and tissue containment method that creates a working space allowing for direct visualization during a power morcellation procedure following a laparoscopic procedure for the excision of benign gynecologic tissue that is not suspected to contain malignancy.

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

TABLE 1—GYNECOLOGIC LAPAROSCOPIC POWER MORCELLATION CONTAINMENT SYSTEM RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measure
Adverse tissue reaction	Biocompatibility.
Infection	Sterilization validation, shelf life validation, and labeling.
Intraperitoneal tissue dissemination (benign or malignant): • Material permeability; • Improper function of containment device; • Inadequate material strength; • Physical trauma to liner caused by contact with morcellator or grasper/tenaculum; • Damage to liner (intentional or accidental) from instrument inserted through secondary port; • Tearing during removal with loss of contents into abdominal cavity; and • Use error.	Non-clinical performance testing (bench and animal), shelf life validation, labeling, and training.
Traumatic injury to non-target tissue/organ: • Active end of morcellator or grasper/tenaculum breaches liner; • Loss of insufflation; • Inadequate space to perform morcellation; • Inadequate visualization of the laparoscopic instruments and tissue specimen relative to the external viscera; and • Use error.	Non-clinical performance testing (bench and animal), labeling, and training.
Hernia through abdominal wall incision	Labeling and training.
Prolongation of procedure and exposure to anesthesia	Labeling and training.

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

A gynecologic laparoscopic power morcellation containment system 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 gynecologic laparoscopic power morcellation containment system they intend to market.

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.

IV. Reference

The following reference is on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also

available electronically at *http://www.regulations.gov.*

1. DEN150028: De novo request from Advanced Surgical Concepts, dated June 19, 2015.

List of Subjects in 21 CFR Part 884

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 884 is 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, 371.

■ 2. Add § 884.4050 to subpart E to read as follows:

§ 884.4050 Gynecologic laparoscopic power morcellation containment system.

(a) *Identification.* A gynecologic laparoscopic power morcellation containment system is a prescription device consisting of an instrument port and tissue containment method that creates a working space allowing for direct visualization during a power morcellation procedure following a laparoscopic procedure for the excision of benign gynecologic tissue that is not suspected to contain malignancy.

(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;

(2) Device components that are labeled sterile must be validated to a sterility assurance level of 10^{-6};

(3) Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components, package integrity, and device functionality over the intended shelf life;

(4) Non-clinical performance data must demonstrate that the device meets all design specifications and performance requirements. The following performance characteristics must be tested:

(i) Demonstration of the device impermeability to tissue, cells, and fluids;

(ii) Demonstration that the device allows for the insertion and withdrawal of laparoscopic instruments while maintaining pneumoperitoneum;

(iii) Demonstration that the containment system provides adequate space to perform morcellation and adequate visualization of the laparoscopic instruments and tissue specimen relative to the external viscera;

(iv) Demonstration that intended laparoscopic instruments and morcellators do not compromise the integrity of the containment system; and

(v) Demonstration that intended users can adequately deploy the device, morcellate a specimen without compromising the integrity of the device, and remove the device without spillage of contents;

(5) Training must be developed and validated to ensure users can follow the instructions for use; and

(6) Labeling must include the following:

(i) A contraindication for use in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy;

(ii) Unless clinical performance data demonstrates that it can be removed or modified, a contraindication for removal of uterine tissue containing suspected fibroids in patients who are: Peri- or postmenopausal, or candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision;

(iii) The following boxed warning: ''Warning: Information regarding the potential risks of a procedure with this device should be shared with patients. Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk.''

(iv) A statement limiting use of device to physicians who have completed the training program; and

(v) An expiration date or shelf life.

Dated: June 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14627 Filed 6–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 40, 41, and 44

[Docket No. TTB–2013–0006; T.D. TTB–137; Re: T.D. TTB–115; Notice No. 137; T.D. ATF–421; T.D. ATF–422; ATF Notice Nos. 887 and 888]

RIN 1513–AB37

Importer Permit Requirements for Tobacco Products and Processed Tobacco, and Other Requirements for Tobacco Products, Processed Tobacco and Cigarette Papers and Tubes

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau is adopting as a final rule, without change, a temporary rule concerning permit and other requirements related to importers and manufacturers of tobacco products and processed tobacco published in the **Federal Register** on June 27, 2013. The regulatory amendments adopted in this final rule include an extension in the duration of new permits for importers of tobacco products and processed tobacco from three years to five years, a technical correction amending the definition of ''Manufacturer of tobacco products'' to reflect a statutory change, and a technical correction related to references to the sale price of large cigars. This final rule also permanently incorporates and reissues other TTB regulations pertaining to importer permit requirements for tobacco products as well as minimum manufacturing and marking requirements for tobacco products and cigarette papers and tubes that also were incorporated in the June 27, 2013, temporary rule.

DATES: Effective July 21, 2016, the temporary regulations published in the **Federal Register** as T.D. TTB–115 at 78 FR 38555 on June 27, 2013, are adopted as final, and those temporary regulations will no longer have a sunset date of August 26, 2016.

FOR FURTHER INFORMATION CONTACT: Jessie Longbrake, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, Box 12, Washington, DC 20005; telephone 202–453–2265; email *TobaccoRegs@ttb.gov.*

SUPPLEMENTARY INFORMATION: