(9) *Person* means any individual, partnership, corporation, trust, estate, cooperative, association, government, or governmental subdivision or agency, or other entity.

* * * * *

■ 32. Amend § 41.91 by revising paragraph (a) and adding paragraph (b)(3) to read as follows:

§ 41.91 Duties of card issuers regarding changes of address.

(a) *Scope.* This section applies to an issuer of a debit or credit card (card issuer) that is a national bank; a Federal savings association; a Federal branch or agency of a foreign bank; or an operating subsidiary of any of these institutions that is not a functionally regulated subsidiary within the meaning of section 5(c)(5) of the Bank Holding Company Act of 1956, as amended (12 U.S.C. 1844(c)(5)).

(b) * * *

(3) *Consumer* means an individual.

* * * * *

■ 33. Add § 41.92 to read as follows:

§ 41.92 Examples.

The examples in Appendix J and Supplement A to Appendix J are not exclusive. Compliance with an example, to the extent applicable, constitutes compliance with this subpart. Examples in a paragraph illustrate only the issue described in the paragraph and do not illustrate any other issue that may arise in this subpart.

Appendices C and E to Part 41 [Removed and Reserved]

■ 34. Remove and reserve Appendixes C and E to part 41.

Appendix J to Part 41 [Amended]

■ 35. Amend Appendix J to part 41 by:

■ a. In section III, paragraph (a), removing the phrase ''(31 CFR 1020.220)''; and

■ b. In item 3. of Supplement A to Appendix J, removing the phrase ''as defined in § 41.82(b)'' and adding in its place the phrase ''as defined in 12 CFR 1022.82(b)''.

PART 133 [REMOVED]

■ 36. Remove part 133.

PART 136 [REMOVED]

■ 37. Remove part 136.

PART 160—LENDING AND INVESTMENT

■ 38. Revise the authority citation for part 160 to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1467a, 1701j–3, 1828, 3803, 3806, 5412(b)(2)(B); 42 U.S.C. 4106.

§ 160.60 [Amended]

■ 39. In § 160.60, amend paragraph (c)(1)(i) by removing the phrase ''part 164 of this chapter'' and adding in its place ''part 34, subpart C of this chapter''.

§ 160.172 [Amended]

■ 40. Amend § 160.172 by removing the phrase ''part 164 of this chapter'' and adding in its place ''part 34, subpart C of this chapter''.

PART 163—SAVINGS ASSOCIATIONS—OPERATIONS

■ 41. Revise the authority citation for part 163 to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1467a, 1817, 1820, 1828, 1831o, 3806, 5101 *et seq.*, 5412(b)(2)(B); 31 U.S.C. 5318; 42 U.S.C. 4106.

§ 163.177 [Removed]

■ 42. Remove § 163.177.

PART 164 [REMOVED]

■ 43. Remove part 164.

PART 171 [REMOVED]

■ 44. Remove part 171.

PART 196 [REMOVED]

■ 45. Remove part 196.

Date: May 13, 2014.

Thomas J. Curry,

Comptroller of the Currency.

[FR Doc. 2014–11406 Filed 5–15–14; 8:45 am]

BILLING CODE 4810–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2014–N–0431]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Colon Capsule Imaging System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the colon capsule imaging 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 colon capsule imaging 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 16, 2014. The classification was effective beginning January 29, 2014.

FOR FURTHER INFORMATION CONTACT: Irene Bacalocostantis, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G244, Silver Spring, MD 20993–0002, 301–796–6814.

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, July 9, 2012), 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 (21 U.S.C. 360) 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) 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.

Given Imaging Ltd. submitted a request on November 21, 2012, for classification of the PillCam® COLON 2 capsule endoscopy system 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) 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 de novo 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 January 29, 2014, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 876.1330 (21 CFR 876.1330).

Following the effective date of this final classification administrative order, any firm submitting a premarket notification (510(k)) for a colon capsule imaging system will need to comply with the special controls named in the final administrative order.

The device is assigned the generic name colon capsule imaging system, and it is identified as a prescription, single-use ingestible capsule designed to acquire video images during natural propulsion through the digestive system. It is specifically designed to visualize the colon for the detection of polyps. It is intended for use only in patients who had an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible.

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—COLON CAPSULE IMAGING SYSTEM RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measure
Adverse tissue reaction	Biocompatibility.
Equipment, malfunction leading to injury	Electrical safety, thermal and mechanical safety. Software validation, verification, and hazard analysis. Non-clinical testing. Labeling.
Interference with other devices and with this device (e.g., interference with image acquisition, patient information compromised).	Electromagnetic compatibility testing. Software validation, verification, and hazard analysis. Non-clinical testing.
Poor image acquisitions	Optical imaging performance testing Non-clinical testing. Labeling.
Failure to excrete	Labeling.
Misinterpretation of the captured images	Clinical performance data. Non-clinical testing. Labeling.
Possibility of missing a polyp, or falsely identifying a polyp	Clinical performance data. Software validation, verification, and hazard analysis. Labeling.
Abdominal pain, nausea, vomiting, choking	Clinical performance data. Labeling.

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

- The capsule must be demonstrated to be biocompatible.
- Non-clinical testing data must demonstrate the mechanical and functional integrity of the device under physically stressed conditions. The following performance characteristics must be tested and detailed protocols must be provided for each test:

○ Bite test to ensure that the capsule can withstand extreme cases of biting.

○ pH resistance test to evaluate integrity of the capsule when exposed to a range of pH values.

○ Battery life test to demonstrate that the capsule's operating time is not constrained by the battery capacity.

□ Shelf-life testing to demonstrate that the device performs as intended at the proposed shelf-life date.

○ Optical testing to evaluate fundamental image quality characteristics such as resolution, field of view, depth of field, distortion, signal-to-noise ratio, uniformity, and image artifacts. A test must be performed to evaluate the potential of scratches, caused by travelling through the gastrointestinal tract, on the transparent window of the capsule and their impact on the optical and color performance.

○ An optical safety analysis must be performed based on maximum (worst-case) light exposure to internal gastrointestinal mucosa, and covering ultraviolet, visible, and near-infrared ranges, as appropriate. A mitigation analysis must be provided.

○ A color performance test must be provided to compare the color differences between the input scene and output image.

○ The video viewer must clearly present the temporal or spatial relationship between any two frames as a real-time lapse or a travel distance. The video viewer must alert the user when the specific video interval is captured at a frame rate lower than the nominal one due to communication errors.

○ A performance test evaluating the latency caused by any adaptive algorithm such as adjustable frame rate must be provided.

○ If the capsule includes a localization module, a localization performance test must be performed to verify the accuracy and precision of locating the capsule position within the colon.

○ A data transmission test must be performed to verify the robustness of the data transmission between the capsule and the recorder. Controlled signal attenuation should be included for simulating a non-ideal environment.

○ Software validation, verification, and hazards analysis must be provided.

○ Electrical equipment safety, including thermal and mechanical safety and electromagnetic compatibility (EMC) testing must be performed. If the environments of intended use include locations outside of hospitals and clinics, appropriate higher immunity test levels must be used. Labeling must include appropriate EMC information.

○ Information demonstrating immunity from wireless hazards.

• The clinical performance characteristics of the device for the detection of colon polyps must be established. Demonstration of the performance characteristics must include assessment of positive percent agreement and negative percent agreement compared to a clinically-acceptable alternative structural imaging method.

• Clinician labeling must include:

○ Specific instructions and the clinical and technical expertise needed for the safe use of the device.

○ A detailed summary of the clinical testing pertinent to use of the device, including the percentage of patients in which a polyp was correctly identified by capsule endoscopy, but also the percent of patients in which the capsule either missed or falsely identified a polyp with respect to the clinically acceptable alternative structural imaging method.

○ The colon cleansing procedure.

○ A detailed summary of the device technical parameters.

○ A detailed summary of the device- and procedure-related complications pertinent to use of the device.

○ An expiration date/shelf life.

• Patient labeling must include:

○ An explanation of the device and the mechanism of operation.

○ Patient preparation procedure.

○ A brief summary of the clinical study. The summary should not only include the percentage of patients in which a polyp was correctly identified by capsule endoscopy, but also the percent of patients in which the capsule either missed or falsely identified a polyp with respect to the clinically acceptable alternative structural imaging method.

○ A summary of the device- and procedure-related complications pertinent to use of the device.

Colon capsule imaging systems are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. (Proposed § 876.1330(a); see section 520(e) of the FD&C Act (21 U.S.C. 360j(e)) and § 801.109 (21 CFR 801.109) (Prescription devices).) Prescription-use restrictions are a type of general controls as defined in section 513(a)(1)(A)(i) of the FD&C Act.

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 prostate lesion documentation 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 administrative 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 has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.*

1. K123666: De Novo Request per 513(f)(2) of the Federal Food, Drug, and Cosmetic Act from Given Imaging Ltd., dated November 21, 2012.

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 21 CFR part 876 continues to read as follows:

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

■ 2. Add § 876.1330 to subpart B to read as follows:

§ 876.1330 Colon capsule endoscopy system.

(a) *Identification.* A prescription, single-use ingestible capsule designed to acquire video images during natural propulsion through the digestive system. It is specifically designed to visualize the colon for the detection of polyps. It is intended for use only in patients who had an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible.

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

(1) The capsule must be demonstrated to be biocompatible.

(2) Non-clinical testing data must demonstrate the mechanical and functional integrity of the device under physically stressed conditions. The following performance characteristics

must be tested and detailed protocols must be provided for each test:

(i) Bite test to ensure that the capsule can withstand extreme cases of biting.

(ii) pH resistance test to evaluate integrity of the capsule when exposed to a range of pH values.

(iii) Battery life test to demonstrate that the capsule's operating time is not constrained by the battery capacity.

(iv) Shelf-life testing to demonstrate that the device performs as intended at the proposed shelf-life date.

(v) Optical testing to evaluate fundamental image quality characteristics such as resolution, field of view, depth of field, distortion, signal-to-noise ratio, uniformity, and image artifacts. A test must be performed to evaluate the potential of scratches, caused by travelling through the gastrointestinal tract, on the transparent window of the capsule and their impact on the optical and color performance.

(vi) An optical safety analysis must be performed based on maximum (worst-case) light exposure to internal gastrointestinal mucosa, and covering ultraviolet, visible, and near-infrared ranges, as appropriate. A mitigation analysis must be provided.

(vii) A color performance test must be provided to compare the color differences between the input scene and output image.

(viii) The video viewer must clearly present the temporal or spatial relationship between any two frames as a real-time lapse or a travel distance. The video viewer must alert the user when the specific video interval is captured at a frame rate lower than the nominal one due to communication errors.

(ix) A performance test evaluating the latency caused by any adaptive algorithm such as adjustable frame rate must be provided.

(x) If the capsule includes a localization module, a localization performance test must be performed to verify the accuracy and precision of locating the capsule position within the colon.

(xi) A data transmission test must be performed to verify the robustness of the data transmission between the capsule and the recorder. Controlled signal attenuation should be included for simulating a non-ideal environment.

(xii) Software validation, verification, and hazards analysis must be provided.

(xiii) Electrical equipment safety, including thermal and mechanical safety and electromagnetic compatibility (EMC) testing must be performed. If the environments of intended use include locations outside of hospitals and clinics, appropriate higher immunity test levels must be used. Labeling must include appropriate EMC information.

(xiv) Information demonstrating immunity from wireless hazards.

(3) The clinical performance characteristics of the device for the detection of colon polyps must be established. Demonstration of the performance characteristics must include assessment of positive percent agreement and negative percent agreement compared to a clinically acceptable alternative structural imaging method.

(4) Clinician labeling must include:

(i) Specific instructions and the clinical and technical expertise needed for the safe use of the device.

(ii) A detailed summary of the clinical testing pertinent to use of the device, including the percentage of patients in which a polyp was correctly identified by capsule endoscopy, but also the percent of patients in which the capsule either missed or falsely identified a polyp with respect to the clinically acceptable alternative structural imaging method.

(iii) The colon cleansing procedure.

(iv) A detailed summary of the device technical parameters.

(v) A detailed summary of the device- and procedure-related complications pertinent to use of the device.

(vi) An expiration date/shelf life.

(5) Patient labeling must include:

(i) An explanation of the device and the mechanism of operation.

(ii) Patient preparation procedure.

(iii) A brief summary of the clinical study. The summary should not only include the percentage of patients in which a polyp was correctly identified by capsule endoscopy, but also the percent of patients in which the capsule either missed or falsely identified a polyp with respect to the clinically acceptable alternative structural imaging method.

(iv) A summary of the device- and procedure-related complications pertinent to use of the device.

Dated: May 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11173 Filed 5–15–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2014–N–0438]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Intravascular Administration Set, Automated Air Removal System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the intravascular administration set, automated air removal 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 intravascular administration set, automated air removal 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 16, 2014. The classification was effective on March 4, 2014.

FOR FURTHER INFORMATION CONTACT: Alan Stevens, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 2561, Silver Spring, MD 20993–0002, 301–796–6294.

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