AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or BAE Systems (Operations) Limited's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2012–0127R1, dated September 10, 2012, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3139.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (m)(4), (m)(5), and (m)(6) of this AD.

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) BAE Systems (Operations) Limited Service Bulletin ATP–26–016, dated October 4, 2011.

(ii) Kidde Graviner Service Bulletin 26–080, Revision 1, dated July 27, 2011.

(3) For BAE Systems (Operations) Limited service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com*; Internet *http://www.baesystems.com/Businesses/RegionalAircraft/index.htm*.

(4) For Kidde Graviner service information identified in this AD, contact Kidde Graviner Limited, Mathisen Way, Colnbrook, Slough, Berkshire, SL3 0HB, United Kingdom; Telephone: +44 (0)1753 683245, Fax: +44 (0)1753 685040.

(5) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued in Renton, Washington, on July 23, 2015.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–18710 Filed 8–3–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket Nos. FDA–2014–C–1616 and FDA–2015–C–0245]

Listing of Color Additives Exempt From Certification; Mica-Based Pearlescent Pigments; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of July 9, 2015, for the final rule that appeared in the **Federal Register** of June 8, 2015, and that amended the color additive regulations to expand the permitted uses of mica-based pearlescent pigments prepared from titanium dioxide and mica as color additives in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, non-alcoholic cocktail mixers and mixes, and in egg decorating kits for coloring shell eggs.

DATES: Effective date of final rule published in the **Federal Register** of June 8, 2015 (80 FR 32303), confirmed: July 9, 2015.

FOR FURTHER INFORMATION CONTACT: Ellen Anderson, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1309.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 8, 2015 (80 FR 32303), we amended the color additive regulations in § 73.350 *Mica-based pearlescent pigments* (21 CFR 73.350) to expand the permitted uses of mica-based pearlescent pigments prepared from titanium dioxide and mica as color additives in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, non-alcoholic cocktail mixers and mixes, and in egg decorating kits for coloring shell eggs.

We gave interested persons until July 8, 2015, to file objections or requests for a hearing. We received no objections or requests for a hearing on the final rule. Therefore, we find that the effective date of the final rule that published in the **Federal Register** of June 8, 2015, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Office of Food Additive Safety, we are giving notice that no objections or requests for a hearing were filed in response to the June 8, 2015, final rule. Accordingly, the amendments issued thereby became effective July 9, 2015.

Dated: July 29, 2015.

Susan Bernard,

Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

[FR Doc. 2015–18996 Filed 8–3–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2015–N–2526]

Medical Devices; Immunology and Microbiology Devices; Classification of *Trichomonas Vaginalis* Nucleic Acid Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying a *Trichomonas vaginalis* nucleic acid assay into class II (special controls). 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 August 4, 2015. The classification was applicable April 19, 2011.

FOR FURTHER INFORMATION CONTACT: Himani Bisht, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5565, Silver Spring, MD 20993–0002, 301–796–6189.

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.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on April 12, 2011, automatically classifying the APTIMA *Trichomonas vaginalis* Assay in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On April 13, 2011, Gen-Probe Incorporated, submitted a request for de novo classification of the APTIMA *Trichomonas vaginalis* Assay 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 for de novo classification 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 will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 19, 2011, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 866.3860.

Following the effective date of this final classification administrative order, any firm submitting a premarket notification (510(k)) for a *Trichomonas vaginalis* nucleic acid assay will need to comply with the special controls named in the final administrative order.

The device is assigned the generic name *Trichomonas vaginalis* nucleic acid assay, and it is identified as a device that consists of primers, probes, enzymes, and controls for the amplification and detection of trichomonas nucleic acids in endocervical swabs, vaginal swabs, and female urine specimens, from women symptomatic for vaginitis, cervicitis, or urethritis and/or to aid in the diagnosis of trichomoniasis in asymptomatic women. The detection of trichomonas nucleic acids, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of trichomoniasis caused by *Trichomonas vaginalis.*

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks:

TABLE 1—IDENTIFIED RISKS AND REQUIRED MITIGATIONS

Identified risks	Required mitigations
A false positive test result may lead to inappropriate use of antibiotics for treatment.	The FDA document entitled ''Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas vaginalis*'', which addresses this risk through: Specific device description requirements, performance studies, and labeling.
A false negative test result for an individual may lead to a potential delay in treatment.	The FDA document entitled ''Class II Special Controls Guideline: *Trichomonas vaginalis* Nucleic Acid Amplification Test System'', which addresses this risk through: Specific device description requirements, performance studies, and labeling.
Failure of the test to perform properly.	The FDA document entitled ''Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas Vaginalis*'', which addresses this risk through: Labeling.
Failure to properly interpret the test results.	The FDA document entitled ''Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas Vaginalis*'', which addresses this risk through: Labeling

FDA believes that the measures set forth in the special controls guideline entitled ''Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas vaginalis*'' are necessary, in addition to general controls, to mitigate the risks to health described in table 1.

A *Trichomonas vaginalis* nucleic acid assay is a prescription device. 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 type of device 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 *Trichomonas vaginalis* nucleic acid assay they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of 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; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, 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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

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

■ 2. Add § 866.3860 to subpart D to read as follows:

§ 866.3860 Trichomonas vaginalis nucleic acid assay.

(a) *Identification.* A *Trichomonas vaginalis* nucleic acid assay is a device that consists of primers, probes, enzymes, and controls for the amplification and detection of trichomonas nucleic acids in endocervical swabs, vaginal swabs, and female urine specimens, from women symptomatic for vaginitis, cervicitis, or urethritis and/or to aid in the diagnosis of trichomoniasis in asymptomatic women. The detection of trichomonas nucleic acids, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of trichomoniasis caused by *Trichomonas vaginalis.*

(b) *Classification.* Class II (special controls). The special controls are set forth in FDA's guideline document entitled: ''Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas vaginalis;* Guideline for Industry and Food and Drug Administration Staff.'' See § 866.1(e) for information on obtaining this document.

Dated: July 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–19072 Filed 8–3–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA–2015–N–2525]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the External Upper Esophageal Sphincter Compression Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the external upper esophageal sphincter (UES) compression device 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 external UES compression device'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 August 4, 2015. The classification was applicable on March 6, 2015.

FOR FURTHER INFORMATION CONTACT: Sunny Park, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2432, Silver Spring, MD, 20993–0002, 301–796–7059, *sunny.park@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). 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.