Amendment Number 6 Effective Date: August 17, 2009.

Amendment Number 7 Effective Date: December 28, 2009.

Amendment Number 8 Effective Date: May 2, 2012, as corrected on November 16, 2012 (ADAMS Accession No. ML12213A170).

Amendment Number 9 Effective Date: March 11, 2014, superseded by Amendment Number 9, Revision 1, on March 21, 2016.

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Amendment Number 9, Revision 1, Effective Date: March 21, 2016.

Safety Analysis Report (SAR) Submitted by: Holtec International.

SAR Title: Final Safety Analysis Report for the HI–STORM 100 Cask System.

Docket Number: 72–1014.

Certificate Expiration Date: May 31, 2020.

Model Number: HI–STORM 100.

* * * * *

Dated at Rockville, Maryland, this 22nd day of December, 2015.

For the Nuclear Regulatory Commission.

Glenn M. Tracy,

Acting, Executive Director for Operations.

[FR Doc. 2015–33280 Filed 1–5–16; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2015–N–4408]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Intravaginal Culture System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the intravaginal culture 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 intravaginal culture 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 January 6, 2015. The classification was applicable on November 2, 2015.

FOR FURTHER INFORMATION CONTACT: Jason Roberts, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G218, Silver Spring, MD 20993–0002, 240–402–6400, *jason.roberts@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&CAct, 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 February 23, 2015, INVO Bioscience, submitted a request for classification of the INVOcell™ Intravaginal Culture 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 for de novo classification 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 November 2, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 884.6165 (21 CFR 884.6165).

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an intravaginal culture system will need to comply with the special controls named in this final order. The device is assigned the generic name intravaginal culture system, and it is identified as a prescription device intended for preparing, holding, and transferring human gametes or embryos during intravaginal in vitro fertilization (IVF) or intravaginal culture procedures.

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

TABLE 1—INTRAVAGINAL CULTURE SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Damage to gametes and/or embryos or disruption of the IVF process	Nonclinical performance testing. Shelf life testing. Clinical testing. Sterilization validation. Labeling.
Patient injury (e.g., hypersensitivity, toxicity, abrasion, discomfort)	Nonclinical performance testing. Shelf life testing. Biocompatibility. Clinical testing. Sterilization validation. Labeling.
Infection	Sterilization validation. Reprocessing validation. Nonclinical performance testing. Shelf life testing. Clinical testing. Labeling.
Transfer of incorrect embryos to patient	Labeling.

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

Intravaginal culture system devices are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; 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), 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 intravaginal culture system they intend to market.

II. Environmental Impact, No Significant 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. DEN150008: De novo Request per 513(f)(2) from INVO Bioscience, dated February 23, 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 21 CFR part 884 continues to read as follows:

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

■ 2. Add § 884.6165 to subpart G to read as follows:

§ 884.6165 Intravaginal culture system.

(a) *Identification.* An intravaginal culture system is a prescription device intended for preparing, holding, and transferring human gametes or embryos during intravaginal in vitro fertilization or intravaginal culture procedures.

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

(1) Clinical performance testing must demonstrate the following:

(i) Comfort and retention of the intravaginal culture device;

(ii) Adverse vaginal tissue reactions associated with intravaginal culture;

(iii) Maximum number of gametes and/or embryos that can be placed in a device; and

(iv) Rates of embryo development to the designated stage, implantation rates, clinical pregnancy rates, live birth rates, and any adverse events or outcomes.

(2) Nonclinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

(i) Mouse embryo assay testing to assess embryotoxicity by evaluating the gamete and embryo-contacting device components effect on the growth and development of mouse embryos to the blastocyst stage;

(ii) Endotoxin testing on gamete and embryo-contacting components of the device;

(iii) Cleaning and disinfection validation of reusable device components;

(iv) Sterility maintenance of the culture media within the device throughout the vaginal incubation

period and subsequent embryo extraction; and

(v) Ability of the device to permit oxygen and carbon dioxide exchange between the media contained within the device and the external environment throughout the vaginal incubation period.

(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 intended to be provided sterile.

(5) Shelf life testing must demonstrate that the device maintains its performance characteristics and the packaging of device components labeled as sterile maintain integrity and sterility for the duration of the shelf life.

(6) Labeling for the device must include:

(i) A detailed summary of the clinical testing, including device effectiveness, device-related complications, and adverse events;

(ii) Validated methods and instructions for reprocessing of reusable components;

(iii) The maximum number of gametes or embryos that can be loaded into the device;

(iv) A warning that informs users that the embryo development is first evaluated following intravaginal culture; and

(v) A statement that instructs the user to use legally marketed assisted reproductive technology media that contain elements to mitigate the contamination risk (*e.g.,* antibiotics) and to support continued embryonic development over the intravaginal culture period.

(7) Patient labeling must be provided and must include:

(i) Relevant warnings, precautions, and adverse effects and complications;

(ii) Information on how to use the device;

(iii) The risks and benefits associated with the use of the device; and

(iv) A summary of the principal clinical device effectiveness results.

Dated: December 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–33264 Filed 1–5–16; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R07–OAR–2015–0733; FRL–9941–06–Region 7]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Nebraska; Sewage Sludge Incinerators

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve the Clean Air Act (CAA) section 111(d)/129 negative declaration for the state of Nebraska, for existing sewage sludge incinerator (SSI) units. This negative declaration certifies that existing SSI units subject to sections 111(d) and 129 of the CAA do not exist within the jurisdiction of Nebraska. EPA is accepting the negative declaration in accordance with the requirements of the CAA.

DATES: This direct final rule will be effective March 7, 2016, without further notice, unless EPA receives adverse comment by February 5, 2016. If EPA receives adverse comment, we will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2015–0733, to *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Paula Higbee, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at 913–551–7028 or by email at *higbee.paula@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' or ''our'' refer to EPA. This section provides additional information by addressing the following:

I. Background

The CAA requires that state regulatory agencies implement the emission guidelines and compliance times using a state plan developed under sections 111(d) and 129 of the CAA. The general provisions for the submittal and approval of state plans are codified in 40 CFR part 60, subpart B and 40 CFR part 62, subpart A. Section 111(d) establishes general requirements and procedures on state plan submittals for the control of designated pollutants. Section 129 requires emission guidelines to be promulgated for all categories of solid waste incineration units, including SSI units. Section 129 mandates that all plan requirements be at least as protective and restrictive as the promulgated emission guidelines. This includes fixed final compliance dates, fixed compliance schedules, and Title V permitting requirements for all affected sources. Section 129 also requires that state plans be submitted to EPA within one year after EPA's promulgation of the emission guidelines and compliance times.

States have options other than submitting a state plan in order to fulfill their obligations under CAA sections 111(d) and 129. If a State does not have any existing Sewage Sludge Incineration (SSI) units for the relevant emissions guidelines, a letter can be submitted certifying that no such units exist within the State (*i.e.,* negative declaration) in lieu of a state plan. The negative declaration exempts the State from the requirements of subpart B that would otherwise require the submittal of a CAA section 111(d)/129 plan.

On March 21, 2011 (76 FR 15372), the EPA established emission guidelines and compliance times for existing SSI units. The emission guidelines and compliance times are codified at 40 CFR 60, Subpart MMMM. In order to fulfill obligations under CAA sections 111(d) and 129, NDEQ submitted a negative declaration letter to EPA on December 6, 2012. The submittal of this declaration exempts NDEQ from the requirement to