



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA-2017-N-6538]

Obstetrical and Gynecological Devices; Reclassification of Single-Use Female Condom, To Be Renamed Single-Use Internal Condom

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify single-use female condoms, renaming the device to “single-use internal condom,” a postamendments class III device (regulated under product code MBU), into class II (special controls) subject to premarket notification (510(k)). FDA is also identifying the special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is finalizing this reclassification on its own initiative based on new information. FDA is also amending the existing device identification for “female condom,” a preamendments class III device (product code OBY), by renaming the device “multiple-use female condom,” to distinguish it from the “single-use internal condom.” This order reclassifies single-use internal condoms from class III to class II and reduces regulatory burden because these types of devices will no longer be required to submit a premarket approval application (PMA), but can instead submit a less burdensome 510(k) before marketing their device.

DATES: This order is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is 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 21 CFR part 807.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA acting by order can

reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available regulatory authority (see *Bell v. Goddard*, 366 F.2d 177, 181 (7th Cir. 1966); *Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 388-391 (D.D.C. 1991)), or in light of changes in “medical science” (*Upjohn Co. v. Finch*, 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the “new information” to support reclassification under section 513(f)(3) must be “valid scientific evidence,” as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co. v. FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Mfrs. Assoc. v. FDA*, 766 F.2d 592 (D.C. Cir.1985), cert. denied, 474 U.S. 1062 (1986)).

FDA relies upon “valid scientific evidence” in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the “valid scientific evidence” upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c)). Section 520(h)(4) of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device, but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the 510(k) premarket notification requirements, if the Agency determines that premarket notification is not necessary to reasonably assure the safety and effectiveness of the device.

On December 4, 2017, FDA published a proposed order in the *Federal Register* to reclassify the device (82 FR 57174) (the “proposed order”). The period for public comment on the proposed order closed on February 2, 2018. FDA received and has considered 78 comments on the proposed order, as discussed in section II.

## II. Comments on the Proposed Order and FDA Response

### A. Introduction

FDA received 78 public comments in response to the December 4, 2017, proposed order. These comments originated from individual consumers, academia, healthcare professionals, healthcare associations, local governments, and industry. The overwhelming majority of commenters supported the proposed reclassification, name change, and the general effort to increase patient access to single-use internal condoms.

We describe and respond to the comments in section B, below. The order of response to the commenters is purely for organizational purposes and does not signify the comment’s value or importance nor the order in which comments were received. Certain comments are grouped together under a single number because the subject matter is similar.

### B. Description of Comments and FDA Response

(Comment 1) Several commenters supported the reclassification and name change, but did not think a contraceptive effectiveness study should be required as a special control. These commenters believe that an acute failure modes study would be sufficient to ensure the safety and effectiveness of single-use internal condoms. The commenters indicated that requiring a

contraceptive effectiveness study is burdensome and that the contraceptive effectiveness rate of a previously approved internal condom (FC1 Female Condom) should be leveraged in lieu of this special control. Another commenter suggested that single-use internal condoms be evaluated based on data from an acute failure modes study because this is the clinical evidence used to support clearance of male condoms made of synthetic materials. Finally, a different commenter agreed with FDA that there are unique considerations for the female condom, and that FDA should carefully consider each single-use internal condom to determine the appropriate method for clinical validation. The commenter noted that the majority of clinical studies published worldwide are conducted using male condoms, and that analysis by FDA, National Institutes of Health, and the Centers for Disease Control and Prevention re-confirmed the safety and effectiveness of male condoms. This commenter recommended that FDA consider developing a medical device development tool to find less burdensome ways of evaluating internal condom effectiveness using biomarkers.

(Response 1) While the probable risks to health and risk mitigations are similar between male and single-use internal condoms, the failure modes are not the same between these two types of condoms. Male condoms have failure modes from slippage and breakage, while single-use internal condoms have failure modes that include slippage, breakage, misdirection, and invagination. FDA believes that a contraceptive effectiveness study is necessary to mitigate the risk of an undesired pregnancy because internal condoms have distinct design features from male condoms (e.g., internal and external retaining mechanisms) and from other internal condoms that can only be evaluated through a contraceptive effectiveness study. Accordingly, FDA believes that the clinical evidence from male condoms and other internal condoms cannot be leveraged to mitigate the risk of undesired pregnancy for an individual single-use internal condom. The

contraceptive effectiveness rate of an individual internal condom is important because internal condoms are intended for the prevention of pregnancy, and this contraceptive effectiveness rate is important for consumers when deciding which method of contraception is most appropriate for them. FDA is not aware of any information, and none was provided to the docket, supporting that a biomarker method could be used in lieu of a contraceptive effectiveness study.

(Comment 2) One commenter generally agreed with FDA's proposed reclassification, name change, and the proposed special controls for single-use internal condoms. This commenter stated that, in addition to FDA's proposed special controls, a pre-clearance good manufacturing practices (GMP) inspection should be required under section 513(f)(5) of the FD&C Act.

(Response 2) FDA may withhold 510(k) clearance under section 513(f)(5) of the FD&C Act if there is a substantial likelihood that failure to comply with GMPs will potentially present a serious risk to human health. FDA does not believe the threshold for pre-clearance GMP inspections is met for single-use internal condoms. Single-use internal condoms will be required to comply with GMPs under the quality system regulation per 21 CFR part 820 that will, in part, mitigate the identified probable risks to health. FDA believes that the special controls identified in this final order, in addition to general controls, including compliance with GMPs, will provide reasonable assurance of safety and effectiveness for single-use internal condoms.

(Comment 3) Multiple commenters requested that FDA not change contraceptive coverage policies for single-use internal condoms.

(Response 3) Contraceptive coverage policies by private insurance payers and the Centers for Medicare & Medicaid Services are outside the scope of FDA's reclassification process. FDA is required to classify devices based on the regulatory controls necessary to

provide reasonable assurance of device safety and effectiveness. FDA believes that sufficient information exists to establish special controls that, in addition to general controls, can provide reasonable assurance of safety and effectiveness for single-use internal condoms.

(Comment 4) Several comments received were related to consumer access and education. One commenter expressed concerns that consumers “believe that all medical-like devices that are placed on the shelves have been reviewed and tested.” Based on safety and effectiveness information provided to the docket, the commenter believes that more attention should be geared towards educating consumers on the proper use and effectiveness of single-use internal condoms. Conversely, several different commenters stated that single-use internal condoms should be made over-the-counter (OTC) devices.

(Response 4) The single-use internal condom is not restricted to prescription use in accordance with 21 CFR 801.109. Single-use internal condoms are OTC devices because FDA believes that adequate directions for lay use can be developed in accordance with 21 CFR 801.5. Adequate directions for use are those under which the layman can use a device safely and for the purposes for which it is intended. This information helps consumers understand how to appropriately use the device and make informed decisions regarding its use. While the devices are OTC, single-use internal condoms will be subject to FDA premarket review in accordance with section 510(k) of the FD&C Act. In accordance with section 513(i) of the FD&C Act, FDA reviews appropriate clinical or scientific data as part of the substantial equivalence determination.

(Comment 5) One commenter stated that single-use internal condoms should be class III “based on medical evidence of its effectiveness in disease prevention as well as a safe and effective family planning method.” The commenter believed that the reclassification is not based

on science, that the reclassification is based on a political stance on birth control, and that science should be the only reason for reclassification. Three commenters included a combination of scientific literature, marketing data, non-public clinical data, and anecdotal information on one single-use internal condom used in the United States and another used outside the United States as additional evidence in support of FDA's reclassification.

(Response 5) FDA is only authorized to use valid scientific evidence to support device reclassification, in accordance with 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). The commenter not supportive of the proposed reclassification did not provide specific information or rationales regarding why FDA's proposal to reclassify was not based on valid scientific evidence. As outlined in the proposed order, sufficient valid scientific evidence exists to establish special controls to provide reasonable assurance of the safety and effectiveness for single-use internal condoms, despite these condoms being for a use which is of substantial importance in preventing impairment of human health. Therefore, FDA believes that single-use internal condoms meet the statutory definition of class II (special controls).

(Comment 6) One commenter requested clarification regarding differences in how male condoms are regulated in comparison to single-use internal condoms.

(Response 6) A male condom is comprised of a sheath which completely covers the penis with a closely fitting membrane. Male condoms are regulated under 21 CFR 884.5300 and are class II (special controls). As of the effective date of this reclassification order, single-use internal condoms are class II (special controls). FDA has identified distinct special controls for single-use internal condoms because they have different failure modes due to differences in technological characteristics compared to male condoms.

### III. The Final Order

FDA is adopting its findings under section 513(f)(3) of the FD&C Act, as published in the preamble to the proposed order (82 FR 57174). FDA is issuing this final order to reclassify single-use female condoms from class III to class II, rename them “single-use internal condoms,” and establish special controls by revising 21 CFR part 884. In this final order, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls, provide a reasonable assurance of the safety and effectiveness for single-use internal condoms. FDA is also amending the existing device identification for female condoms to distinguish them from single-use internal condoms, by renaming the device “multiple-use female condom.” The Agency is making two minor modifications to the identification for single-use internal condoms by confirming that they are OTC devices and that the device is intended to “prevent the transmission of sexually transmitted infections,” not “prevent sexually transmitted infections.”

FDA may exempt a class II device from the premarket notification requirements, under section 510(m) 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 devices. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of single-use internal condoms, and therefore, this device type is not exempt from premarket notification requirements.

The device is assigned the generic name single-use internal condom, and it is identified as an OTC sheath-like device that lines the vaginal or anal wall and is inserted into the vagina or anus prior to the initiation of coitus. At the conclusion of coitus, it is removed and discarded. It is indicated for contraception and/or prophylactic (preventing the transmission of sexually transmitted infections) purposes.

Under this final order, the single-use internal condom is an OTC device. OTC devices must bear adequate directions for lay use as outlined in 21 CFR 801.5. Under 21 CFR 807.81, the device would continue to be subject to 510(k) requirements.

#### IV. Analysis of Environmental Impact

We have 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.

#### V. 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 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

#### 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, 360l, 371.

2. Amend § 884.5330 by revising the section heading and paragraph (a) to read as follows:

§ 884.5330 Multiple-use female condom.

(a) *Identification.* A multiple-use female condom is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. At the conclusion of coitus, the device can be reused. It is indicated for contraception and prophylactic (preventing the transmission of sexually transmitted infections) purposes.

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3. Add § 884.5340 to subpart F to read as follows:

§ 884.5340 Single-use internal condom.

(a) *Identification.* A single-use internal condom is an over-the-counter sheath-like device that lines the vaginal or anal wall and is inserted into the vagina or anus prior to the initiation of coitus. At the conclusion of coitus, it is removed and discarded. It is indicated for contraception and/or prophylactic (preventing the transmission of sexually transmitted infections) purposes.

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

(1) Clinical performance testing must evaluate the following:

(i) Rate of clinical failure of the device and rate of individual failure modes of the device based on an acute failure modes study evaluating the intended use (vaginal and/or anal intercourse); and

(ii) Cumulative pregnancy rate when using the device based on a contraceptive effectiveness study (when the device is indicated for vaginal intercourse).

(2) Viral penetration testing must demonstrate the device is an effective barrier to sexually transmitted infections.

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

(i) Mechanical testing must demonstrate the device can withstand forces under anticipated use conditions, include evaluation of tensile, tear, and burst properties of the device; and

(ii) Compatibility testing with personal lubricants must determine whether the physical properties of the device are adversely affected by use of additional lubricants.

(4) The device must be demonstrated to be biocompatible.

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

(6) Labeling of the device must include:

(i) Contraceptive effectiveness table comparing typical use and perfect use pregnancy rates with the device to other available methods of birth control;

(ii) Statement regarding the adverse events associated with the device, including potential transmission of infection, adverse tissue reaction, and ulceration or other physical trauma;

(iii) Expiration date; and

(iv) Statement regarding compatibility with additional types of personal lubricants.

Dated: September 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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