4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 884**

**[Docket No. FDA-2026-N-4659]**

# Medical Devices; Obstetrical and Gynecological Devices; Classification of the External Condom for Anal Intercourse or Vaginal Intercourse

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the external condom for anal intercourse or vaginal intercourse into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the external condom for anal intercourse or vaginal intercourse. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

**DATES:** This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The classification was applicable on February 23, 2022.

**FOR FURTHER INFORMATION CONTACT:** Sharon Andrews, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2640, Silver Spring, MD 20993-0002, 301-796-6529, Sharon.Andrews@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Upon request, FDA (the Agency or we) has classified the external condom for anal intercourse or vaginal intercourse into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the device. In addition, we believe

this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the

device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

## II. De Novo Classification

On December 9, 2021, FDA received Global Protection Corp.'s request for De Novo classification of the ONE Male Condom. 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.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see

section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 23, 2022, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 884.5305.[1] We have named the generic type of device "external condom for anal intercourse or vaginal intercourse," and it is identified as a barrier device which covers the penis and is used to prevent the transmission of sexually transmitted infections (when used for anal intercourse or vaginal intercourse) and for contraception (when used for vaginal intercourse). This classification does not include condoms intended for vaginal intercourse only.

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

Table 1.--Risks to Health and Mitigation Measures for External Condom for Anal Intercourse or Vaginal Intercourse

| Identified Risks to Health | Mitigation Measures |
|---|---|
| Transmission of sexually transmitted infection | Acute failure modes clinical study;<br>Non-clinical performance testing;<br>Shelf life testing; and<br>Labeling |
| Pregnancy | Acute failure modes clinical study;<br>Non-clinical performance testing;<br>Shelf life testing; and<br>Labeling |
| Adverse tissue reaction | Biocompatibility evaluation; and<br>Labeling |
| Mechanical injury leading to ulceration, laceration, trauma | Acute failure modes clinical study;<br>Non-clinical performance testing;<br>Shelf life testing; and<br>Labeling |
| Use error/improper device use leading to the risks above | Acute failure modes clinical study; and<br>Labeling |

[1] FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for external condoms for anal intercourse or vaginal intercourse. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

## III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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. 3501-3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910-0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910-0231; 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 regarding quality management system regulation have been approved under OMB control

number 0910-0073; and the collections of information in 21 CFR part 801 regarding labeling 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. Add § 884.5305 to subpart F to read as follows:

**§ 884.5305 External condom for anal intercourse or vaginal intercourse.**

(a) *Identification*. An external condom for anal intercourse or vaginal intercourse is a barrier device which covers the penis and is used to prevent the transmission of sexually transmitted infections (when used for anal intercourse or vaginal intercourse) and for contraception (when used for vaginal intercourse). This classification does not include condoms intended for vaginal intercourse only.

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

(1) Clinical performance data must demonstrate the total rate of clinical failure and rate of individual failure modes of the device based on an acute failure modes study.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The data must include an assessment of mechanical and material integrity, including an evaluation of device failure modes. For devices made of materials other than natural rubber latex, viral penetration testing must be conducted to evaluate barrier effectiveness to sexually transmitted infections.

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

(4) Performance data must support the shelf life of the device by demonstrating device functionality and package integrity over the identified shelf life.

(5) Labeling must include:

(i) If indicated for vaginal intercourse, a contraceptive effectiveness table comparing typical use and perfect use pregnancy rates with the device to other available methods of birth control;

(ii) Statement regarding compatibility with additional lubricant types;

(iii) Statement regarding the adverse events associated with the device, including transmission of infection, pregnancy, adverse tissue reaction, mechanical injury, or improper device use;

(iv) Expiration date; and

(v) The following information, warnings and precautions:

(A) The sexually transmitted infections (STIs) for which the device is most protective, the degree of protection the device provides against specific types of STIs, and the STIs the device does not protect against;

(B) A statement that the device does not completely eliminate the risks of pregnancy and sexually transmitted infections and that risk can be decreased with correct and consistent use;

(C) A warning regarding the risk of device failure during anal intercourse if adequate lubricant is not used;

(D) A warning stating that the device cannot be used multiple times and is limited to one sex act; and

(E) A precaution stating not to use the device if the user is at risk for material related allergic reactions.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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