K052206

II. 510(k) SUMMARY

Submitted By: CONDAX, LLC
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SEP 12 2006

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Date Prepared: August 5, 2005

Proprietary Name: Zeus™ Male Condom Applicator

Common Name: Condom Applicator

Classification Name: Not Classified

Predicate Device: Kwikeze™ Male Condom Applicator (K031007)

Description of Device: The Zeus™ Male Condom Applicator is a bell shaped pouch that is open at one end and closed at the other. It is molded from polyethylene plastic. The applicator is designed to hold a latex condom in place for correct donning onto an erect penis. All surfaces and edges of the applicator are rounded to prevent damage to condom. Silicone or water-based lubricant is added to the condom prior to packaging.

Approximately 2.5 inches of the condom is unrolled and lies nestled, but not firmly held, within the walls of the applicator. The width of the applicator at the point where the condom is attached is 54mm thus enabling a 52mm (nominal width) condom to be held prior to use without imparting a permanent stretch to the condom. The applicator and condom are packaged and sealed in an aluminum foil wrapper.

The applicator and attached condom are removed together from the package prior to use. The user cups the device in either hand and then, during the application process, squeezes the edges of the applicator which forces the sides to bellow-out, and thus opens the attached condom The device is centered over the head of the penis and is lowered to a point that the penis makes contact with the interior condom wall. The user then uses his thumb to unroll the condom from the applicator and onto the penis. The user continues to unroll the bead as far down the penis as possible. The applicator is removed from the penis and discarded (prior to intercourse).

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Intended Use of the Device:

The Zeus™ Male Condom Applicator facilitates the correct orientation of the condom with respect to the penis and therefore contributes to more effective and correct donning of the condom. Once the condom is positioned on the penis and prior to intercourse, the applicator is discarded.

Technological Characteristics:

The Zeus™ applicator is designed as a SINGLE USE ONLY device. After donning of the condom, the applicator will be discarded; the condom will also be discarded after intercourse. That precaution is included in the Instructions for Use.

Although different in design and appearance, this product has the same basic technological function as the predicate device identified above. Condom(s) used with the device shall have 510(k) clearance and shall conform to ASTM Latex Condom Standard D3492.

Stability: The applicator with attached condom was subjected to accelerated aging conditions to determine the potential shelf-life (expiration date) of the product. Tests were performed on three lots of condoms attached to the applicator after 7 days @70°C and 90 days @50°C. The applicator was also evaluated after conditioning. The results of this study show that both applicator and condoms remained compliant with ASTM D3492 airburst requirements after aging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 12 2006

Condax LLC
c/o Mr. Eli J. Carter
Consultant
1219 Little Creek Road
P.O. Box 12139
DURHAM NC 27709

Re: K052206
Trade/Device Name: Zeus™ Male Latex Condom Applicator
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: July 13, 2006
Received: July 17, 2006

Dear Mr. Carter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name Male Condom Applicator

Indications for Use: The Zeus™ Male Condom Applicator facilitates correct positioning (donning) of a male latex condom prior to sexual intercourse. The condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

Prescription Use _____
(Per 21 CFR 801, Subpart D)

OR

Over-the-Counter Use ✓
(Per 21CFR 801, Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K052206