K031007 NOV 1 4 2003

II. 510(k) SUMMARY

Submitted By: CONDAX, LLC
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Date Prepared: March 27, 2003

Proprietary Name: Kwikeze Male Condom Applicator

Common Name: Condom Applicator

Classification Name: Not Classified

Predicate Device: Mentor Plus Condom; K874383

Description of Device: The Kwikeze™ Male Condom Applicator is an elliptical ring made of polyethylene plastic. When packaged, the applicator is collapsed on self-scored lines in a manner that allows the condom to be loosely positioned within the inner-folds of the ring. The collapsed applicator is held in position with a polyurethane band. The condom is stretched slightly to position it on top of the applicator. This configuration allows the condom to rest un-stretched until time of use. After opening the sealed foil package, and prior to use, the band is removed allowing the ring and condom to expand to its original oval shape. The device when pulled opened expands the attached condom enough to allow for easy insertion and correct positioning of the condom on the erect penis.

Intended Use of the Device:

The Kwikeze™ Male Condom Applicator has the same intended use as the predicate device. The condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases). Both the applicator in the predicate device and the Kwikeze™ Applicator facilitate correct orientation of the condom with respect to the penis and therefore contribute to more effective and correct donning of the condom. Once the condom is positioned on the penis, the applicator is discarded.

Technological Characteristics:

The Kwikeze™ 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 use. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2003

Condax, LLC
% Mr. Eli J. Carter
Consultant
1219 Little Creek Rd.
DURHAM NC 27713

Re: K031007
Trade Name/Device: Kwikeze™ Condom Applicator
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulation Number: 21 CFR 884.5310
Regulation Name: Condom with spermicidal lubricant
Regulatory Class: Class II
Product Code: 85 HIS and LTZ
Dated: October 22, 2003
Received: October 28, 2003

Dear Mr. Carter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

This letter will allow you to begin marketing your device as described in your 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.

Please be advised that, as of March 25, 1998, labeling for latex condoms (21 CFR §884.5300 and §884.5310) must comply with Use Labeling for Latex Condoms: Expiration Dating, 21 CFR 801.435. Therefore, an expiration date, supported by test data developed under the conditions specified in §801.435(d), must be displayed prominently and legibly on condom labeling. For condoms with spermicidal lubricant, the effective shelf life of the spermicide must be compared with the shelf life of the condom and labeled with the earlier of the two expiration dates. Although supporting data is not to be provided in your 510(k) submission, §801.435(j) requires that you maintain this data and that it be available for inspection by FDA. Furthermore, §801.435(e) requires that if your real-time test data fails to confirm the shelf life estimated by the methods in §801.435(d), then you must relabel all product to reflect the actual shelf life. Condoms are not to be labeled with an expiration date that gives a shelf life more than five years.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §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 (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.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

VII. INDICATIONS FOR USE STATEMENT

510(k) Number ~~Not Known~~ K031007

Device Name Male Natural Rubber Latex Condom

Indications for Use: The Kwikeze 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 diseases)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEED
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031007