FEB 2 2000

K993782

II 510(K) SUMMARY

Submitted by: PT Vonix Latexindo
Jl. Balikpapan 21 E Jakarta
Pusat 10160, Indonesia
Phone: 62-21-385 0222/385 0202

Contact Person: Vijay Mahal (Applicant)
Vineel Enterprises
Phone:617-973-7157

Date Prepared: November 4th, 1999

Proprietary Name: Simplex Condoms

Common Name: Latex Condom

Classification Name: Condom (21 CFR 884.5300)

Predicate Device: Condom with Nonoxynol-9
510K# **K974324**

Description of Device: This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom is made of first grade latex material, teat-ended, single wall and contoured. Its dimensions are: length 170mm minimum, width: 51mm, thickness: 0.04-0.06 mm (single wall), weight: 1.0-1.3 gm/piece

Intended Use of the Device: This latex condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

Technological Characteristics: This condom has the same technological characteristics as the predicate condoms identified above. This condom is made of first grade natural rubber latex material using a German- made automatic dipping line. The design of this condom is in conformance with **WHO, ISO, EN 600, DIN** and **ASTM D3492-96**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2000

P.T. Vonix Latexindo
c/o Vijay Mahal, Ph.D.
Vineel Enterprises
7 Riverview Road
Framingham, MA 01701

Re: K993782
Simplex Brand Male Latex Condom
(with Spermicidal Lubricant)
Dated: November 4, 1999
Received: November 8, 1999
Regulatory Class: II
21 CFR §884.5300/Procode: 85 HIS

Dear Dr. Mahal:

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.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 products 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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

for CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

VII. INDICATIONS FOR USE STATEMENT

510(k) Number: Not available yet K993782

Device Name: Simplex brand Male Rubber Latex Condom (With Spermicidal Lubricant)

Indications For Use: The Simplex brand condom is a male contraceptive device, fabricated of natural latex, which is designed to completely cover the penis during sexual intercourse. This condom is intended to be used for contraception and for prophylactics purposes. If used properly, this condom will help reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases including chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B and syphilis. In addition, this condom will help reduce the risk of pregnancy without the serious side effects sometimes associated with other methods. However, no contraceptive can guarantee 100 % effectiveness. Failure to use as directed, may further result in loss of protection. Furthermore, sexually transmitted diseases can be transmitted through lesions and various body fluids, during intimate contact. Therefore, the condom should be applied before any such contact.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓

David C. Dagnon

(Division Sign-Off)
Division of Reproductive, **Abdominal, ENT,** and Radiological Devices
510(k) Number K993782