K060797

APR 7 2006

3. 510(k) Summary (21 CFR §807.92)

Sponsor:	Veraxis Int'l Inc. (or "Veraxis") 9663 Santa Monica Blvd., Suite 2500 Beverly Hills, CA 90210 (646) 285-7714
Contact:	Jules T. Mitchel, President Target Health Inc. 261 Madison Avenue, 24th Floor New York, NY 10016 Tel: (212) 681-2100 Fax: (212) 682-2105 JulesMitchel@TargetHealth.com
Date:	February 23, 2006
Name of the Device:	Trade Name: Naked™ Common Name: Condom Classification Name: Condom 884.5300 Class II (Product Code HIS).
Substantial Equivalence:	The Veraxis Naked™ condom is equivalent in intended use and technological characteristics to Oceans Seven, Intn'l The Official Condom of the 21st Century (They-Fit™) condoms and Church & Dwight, Trojan® Magnum XL condoms.
Device Description:	By creating an actual physical barrier between partners engaged in sexual activity, the condom represents the best available solution to two of the world's major health challenges: sexually transmitted diseases/AIDS and unwanted pregnancy. The design of the condom is essential to its effectiveness. The closed end has a reservoir tip to contain semen. The condom described herein has an integral ring at its base and a snug fit along its lower portion in order to ensure a safe, secure seal and barrier. Although standard condoms are one of the few over-the-counter, non-prescription contraceptives, condoms have many deficiencies that limit their usage among sexually active populations: (i) they are uncomfortable, (ii) they do not transmit sensation well, and (iii) they feel unnatural. As a result, and despite the FDA warnings, the AIDS epidemic, and the high risk involved in unprotected sex, a significant portion of sexually active populations decline to use condoms or use them only occasionally.

The design of the Naked™ condom described herein addresses these deficiencies so that condom usage will significantly improve among sexually active populations. The condom described herein provides a slightly relaxed fit along the main body of the product between the snug base and reservoir tip. This relaxed fit provides a more natural feel during intercourse, an easier application process, and improved sensation, while maintaining a safe, secure seal and barrier.

This product is designed to fully conform to ISO 10993 and ISO 4074. It also conforms to ASTM D3492.

Intended Use:

The Veraxis Int'l Inc. Naked™ condom is to be used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

The Veraxis Int'l Inc. Naked™ condom is indicated for Over-The-Counter Use (21 CFR 801 Subpart C)

Technological Characteristics:

This condom has the same technical characteristics as the predicate condoms identified above. The product described herein features a slightly relaxed fit along the main body of the product. The relaxed fit at the closed end of the condom provides a greater lay flat width than the width of the snug base and safety seal it creates at the open end of the condom. The nature and value of the relaxed fit is well expressed by Ansell Incorporated, the second largest manufacturer of condoms in the world, in an article in *Mens Journal* in April of 1998:

"For 20 years this industry has been telling people that thinner condoms are better, more sensitive, but really, you can't tell the difference between the standard thickness of .07 mm and the thin condom of .05 mm. The real difference is looseness (the relaxed fit), which allows for friction between the penis and the latex and the vaginal wall."

The Naked™ condom comes in a range of sizes that provide increased customization for each individual which makes for a safer, more secure, and better fit. These two technical characteristics (relaxed fit and various sizes) maximize product effectiveness and sensation, and thereby increase product usage among the sexually active populations.

As stated in the product description, this product is designed to fully conform to ISO 10993 and ISO 4074. It also conforms to ASTM D3492.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Veraxis Int'l Inc.
c/o Mr. Jeffrey D. Rongero
Senior Project Engineer
Conformity Assessment Services
Underwriters Laboratories, Inc.
Research Triangle Park Division
12 Laboratory Drive
P.O. Box 13995
RESEARCH TRIANGLE PARK NC 27709-3995

Re: K060797
Trade/Device Name: Naked™ Condom
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: March 17, 2006
Received: March 24, 2006

Dear Mr. Rongero:

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

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/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

K060797

2. Indication for Use

510(k) Number (if known): ~~N/A~~ K060797

Device Name: Naked™ male natural rubber latex condom

Indications For Use: The Veraxis Int'l Inc. Naked™ condom is to be used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060797