K063401

II. **510(k) Summary (Option 1)**
(Refer to 21 CFR §807.92)

MAR 26 2007

Submitted by: Medtech Products Limited
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Contact Person: Dr. A.V.K. Reddy

Date Prepared: October 23, 2006

Proprietary Name: **BANANA Ribbed**

Common Name: Latex Condom

Classification Name: Condom (21 CFR §884.5300)

Predicate Device: Latex Condoms, with silicone oil lubricant and straight wall like Life styles Snugger fit condom, Durex love condom and Trojan extended pleasure.

Description of the Device: This condom is made of natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom has smooth surface on the body, curve-sided, reservoir ended, straight six ribbed line at closed end, nominal length, width, thickness condoms with an integral bead at the open end.

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 condom identified above. This condom design is in conformance with standard specification for Rubber contraceptives (male condoms) ASTM D 3492: 2003. This condom is made of natural rubber latex.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Dr. A.V. K. Reddy
Chairman and Managing Director
MedTech Products Ltd.
5876 155th Ave. SE
BELLEVUE WA 98006

MAR 26 2007

Re: K063401
Trade/Device Name: BANANA Ribbed Male Natural Rubber Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: March 10, 2007
Received: March 13, 2007

Dear Dr. Reddy:

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

VII. INDICATIONS FOR USE STATEMENT

510(K) Number : K063401

Device Name : BANANA Ribbed Male Natural Rubber Latex Condom

Indications for use : The BANANA Ribbed condom is used for contraception 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 NEEDED)

Concurrence of CDRH, Office of Devices Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR §801.109)

David A. Krupinski

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063401