OCT 2 5 2002

Attachment #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K021186

1. **Submitter's Identification:**

   Condomi Erfert Prdoktionsgesellschaft mbH
   Tiergartenstafβe2, DF-99089 Erfert, Germany

   Date Summary Prepared:

   April 11, 2002

2. **Name of the Device:**

   Condomi Nature condoms, transparent, lubricated with silicon oil

   Condomi Stimulation condoms, colored pink, studded, lubricated with silicon oil

   Condomi vanilla Gold condoms, colored gold, lubricated with silicon oil, and vanilla flavor.

   Condomi SuperSafe condoms, transparent, form-fitting, lubricated with spermicide, N-9.

   Condomi XXL condoms, transparent, extra large condom, lubricated with silicon oil

   Condomi Strong, condoms, transparent, extra thick condom, lubricated with silicon oil

3. **Predicate Device Information:** Comparison to Legally Marketed Device:

   Exhibit 6 are lists of recently submitted and cleared 510(k) s for male latex condoms (part 1), and male latex condoms with spermicidal lubricant (part 2) These lists were obtained from the FDA/CDRH 510(k) database and include condoms that are transparent, colored, flavored and lubricated with silicone or N-9 spermicidal lubricant. The Condomi brand condoms are similar in design,

composition, function, technological characteristics, and intended use to these condoms.

4. **Device Description:** Like other natural latex condoms on the market, the Condomi brand condoms are latex sheaths, which completely cover the penis with a closely fitting membrane. The following condom styles, colors, and flavors will be offered:

   a) Standard transparent lubricated with silicon oil
   b) Colored pink, studded, lubricated with silicon oil
   c) Colored gold, lubricated with silicon oil, and vanilla flavor.
   d) Transparent, form-fitting condom, lubricated with spermicidal lubricant N-9
   e) Extra large condom transparent, lubricated with silicon oil
   f) Extra strong condom, transparent, lubricated with silicon oil

5. **Intended Use:** : Condomi brand latex condoms are intended to be used as a contraceptive (for the prevention of pregnancy) and/or for the prevention of the transmission of sexually transmitted diseases.

6. **Comparison to Predicate Devices:** There are no significant differences between Condomi brand condoms and the predicates.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**
   The Agency has recognized ASTM D3492-97, Standard Specifications for Rubber Contraceptives (male condoms); ISO Standard 4074, Requirements for Rubber Condoms, parts 1,2,3,5,6,7,9 1996; and ISO 10993, Biological Evaluation of Medical Devices as Consensus standards. The Condomi brand condoms meet these standards. Methods and results were provided.

8. **Discussion of Clinical Tests Performed:**
   No clinical testings were completed

9. **Conclusions:** The Condomi brand condoms are safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2002

Ms. Carolann Kotula
Vice President RA/QA
mdi Consultants, Inc.
55 Northern Blvd.
GREAT NECK NY 11021

Re: K021186
Trade Name/Device: Condomi® Brand Male Latex Condoms
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulation Number: 21 CFR 884.5310
Regulation Name: Condom with spermicidal lubricant
Regulatory Class: II
Product Code: 85 HIS and LTZ
Dated: July 30, 2002
Received: August 5, 2002

Dear Ms. Kotula:

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. 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, 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,

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

Attachment # 3

510(k) Number (if known): K021186

Device Name: Condomi brand male latex condoms

Indications For Use: Condomi brand latex condoms are intended to be used as a contraceptive (for the prevention of pregnancy) and/or for the prevention of the transmission of sexually transmitted diseases.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021186