K091769

510(k) SUMMARY

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FEB – 5 2010

Date Prepared: June 10, 2009

Proprietary Name: Trust Dams

Common Name: Latex Dams

Classification Name: Latex Dams

Predicate Devices: Sheer Glyde Dams
K990067

Description of Device: This oral dam is made of natural rubber latex, which completely covers a person's pubic areas during oral genital stimulation. This dam has a smooth surface (both sides), nominal lay flat width 154 mm, nominal length 250 mm, and nominal thickness 0.07mm. It is non- lubricated, and food grade cornstarch is used as a dressing material.

The condoms from which the oral dams are made conform to current established national and international voluntary standards which include ASTM D3492:2008; and have been previously cleared by the USFDA (ref: K070830).

The condoms will be offered in the following Colors and Flavors:

	Color	Flavor
1.	Yellow	Banana
2.	Red	Strawberry
3.	Green	Mint

Indications for Use: The Line One Trust Dam is used as a barrier when engaging in oral/vaginal sex and oral/anal sex to help reduce the transmission of bodily fluids, harmful germs, and sexually transmitted diseases.

Technological Characteristics:

This oral dam has the same technological characteristics as the listed predicate device identified above. The latex condoms (sheaths) from which the dams are made conform with the ASTM D3492:2008 Male Latex Condom Standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 5 2010

Line One Laboratories, Inc.
c/o Mr. Eli Carter
Consultant
Eli Carter & Associates
P.O. Box 12139
DURHAM NC 27709

Re: K091769
Trade Name: Trust Dam
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MSC
Dated: January 25, 2010
Received: January 28, 2010

Dear Mr. Carter:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K 091769

Device Name: **Line One Trust Dam**

Indications for Use: The Line One Trust Dam is used as a barrier when engaging in oral/vaginal sex and oral/anal sex to help reduce the transmission of bodily fluids, harmful germs, and sexually transmitted diseases.

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K091769

(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)