

K051842

510 – K SUMMARY

APR 14 2006

Submitted by CUPID CONDOM LIMITED
A – 68, M.I.D.C. (Malegaon)
Sinnar, Nasik – 422133
Maharashtra, INDIA

Contact Person Mr. K.K. GOYAL / Mr. O.P. GARG

Date Prepared 30th June 2005

Proprietary Name GREEN LOVE

Common Name Natural Latex, silicone lubricated, reservoir
tipped, Condom

Classification Name Condom (21 CFR 884.5300)

Predicate Device KAMA SUTRA Latex Lubricated Condom
510 – K No : K 931077 / B

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 has the specification as enclosed in *Annexure 2*

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 purpose (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 ASTM Latex Condom Standard D 3492-03 and that the condom is made of natural rubber latex



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 14 2006

Mr. K.K. Goyal
C.E.O.
Cupid Condom Ltd.
A-68 M.I.D.C. Sinnar
MALEGAON, Nashik, 422 113
INDIA

Re: K051842
Trade/Device Name: Green Love Male Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: March 10, 2006
Received: March 14, 2006

Dear Mr. Goyal:

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.



Protecting and Promoting Public Health

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.

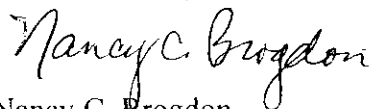
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051842

Device Name: Green Love Male Latex Condom

Indications For Use:

“Condoms are latex sheaths, intended to completely cover the penis during sexual intercourse for contraception and prophylaxis, an aid to the prevention of sexually transmitted diseases (STDs). If used properly, latex Condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases.”

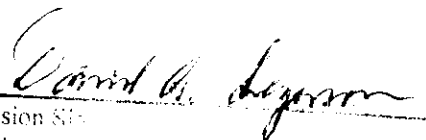
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(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)



(Division Signatory)

Division:
and RAC:

510(k) Number: K051842

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