SEP 16 2009

K083817

Section 7 510(k) Summary(rev.01)

[Refer to 21 CFR 807.92]

Submitted by:	Suzhou Colour-way Enterprise Development Co.,Ltd QA Department Dongqiao Industrial Area, Suzhou, Jiangsu 215152.China,
Contact Person:	Mr.Liu Songling
Date Prepared:	2009-08-20
Proprietary Name:	m. Dior Brand or Private Label
Common Name:	Latex Condoms for Men
Classification Name:	Condom (21 CFR 884.5300)
Predicate Device:	Latex Lubricated Condom 510(k) # K071313
Description of the Device:	The condoms are made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom is designed to conform to the standards including ASTM D3492 and ISO 4074. The condoms are smooth surface straight walled nipple-end (SWNE) style within ASTM standard specifications D-3492 Table 1 requirements, e.g., minimum length 16o mm, maximum width 54 mm, and minimum thickness of 30 μM.
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:	The 510(k) subject condom products have the same technological characteristics as the predicate condom products identified above. The design is in conformance with ASTM Latex Condom Standard D3492 and the condoms are made of natural rubber latex. both are straight-walled, nipple-ended, lubricated condoms and made using the same basic formulations of compounded natural rubber latex.
Indications for Use	M. Dior Brand Latex Condoms are intended to prevent pregnancy, HIV/AIDS, and other sexually transmitted infections. The device is for over the counter use.

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

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Suzhou Colour-way Enterprise Development Co., Ltd.
c/o Mr. Chu Xiaoan
Beijing Easy-Link Company
Room 1606, Bldg. 1, Jianxiang-Yuan No. 209
Bei Si Huan Zhong Road
Haidian District, Beijing 100083
P. R. CHINA

Re: K083817
Trade/Device Name: M. Dior™ Brand Male Latex Condom
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: August 28, 2009
Received: September 1, 2009

Dear Mr. Xiaoan:

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 (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

Section 8 Indications for Use Statement(rev01)

INDICATIONS FOR USE STATEMENT

510(k) Number: K083817

Device Name:

m. Dior Brand Male Natural Rubber Latex Condom

Indications For Use: *m. Dior Brand* Latex Condoms are intended to prevent pregnancy, HIV/AIDS, and other sexually transmitted infections.

The device is for over the counter use.

(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 X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083817