NOTE: *Provide the information required by 21 CFR §807.92, Content and format for a 510(k) summary (Option 1), below*
OR
the 510(k) Statement (Option 2) on the next page.

II. *510(k) SUMMARY (Option 1)*
[Refer to 21 CFR §807.92]

Submitted by: Guilin Latex Factory
Technical Quality Department
No.6 Wushan Road, Guilin, Guangxi, China, 541001
Tel: 86-773-2822279

Contact Person: Jiang Youfan

Date Prepared: Oct.8,1999

Proprietary Name: OSMANTHUS, ~~KONGFU~~, and GOBON

Common Name: Latex Condom

Classification Name: Condom (21 CFR §884.5300)
and / or
Condom with Spermicidal Lubricant (21 CFR §884.5310)

Predicate Device: Latex Lubricated Condom
510(k) #K[######]
and / or
Latex Condom with Spermicidal Lubricant
510(k) #K[######]

Description of the Device: This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom [*include a brief description of the condom, such as, a straight-walled, nipple-end, nominal length, nominal width, nominal thickness, etc*]. See Tab 1

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: [*Indicate whether the condom has the same technological characteristics as the predicate condom identified above. Indicate that the design is in conformance with ASTM Latex Condom Standard D3492 and that the condom is made of natural rubber latex. Summarize the similarities and differences of the features and technological characteristics of the condom in comparison to the predicate condom.*]
See Annex 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2000

Guilin Latex Factory
c/o Mr. Peter Wei
USA Agent
93 Morningside Drive
San Francisco, CA 94132

Re: K994118
Osmanthus and Gobon Natural
Rubber Latex Condom
Dated: May 8, 2000
Received: May 17, 2000
Regulatory Class: II
21 CFR §884.5300/Procode: 85 HIS

Dear Mr. Wei:

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. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known) : K994118

Device Name: Osmanthus and Gobon Male Natural Rubber Latex Condom

Indications For Use: The Osmanthus and Gobon 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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994118

(Optional Format 3-10-98)

Over-the-Counter Use ✓