K972427

510(k) Summary Notification

Submitter: **Custom Services International, Inc.**
3111 Post Rd.
Las Vegas, NV 89118

AUG 20 1997

Telephone Number: (702) 897-1789

Contact: **Lillie C. Thomas, M.S.**
Director of Quality Assurance

Registration Number: **2951584**

Date Submitted: June 26, 1997

Name of the Device: Condom, smooth surface, reservoir end, approximately 180 mm in length and 52 mm in width (Type 1, Style 2, Class A) ***colored*** rubber contraceptive device, nonlubricated or lubricated with silicone.

Trade Names: InnerWear™, Jasmine®, Jimmy-O Raincoat™, Raincoat™, Drink®

Equivalent Device: Applicant Device covered by K963319 (nonlubricated) K963321 (lubricated) and Ansell Inc. Condom, colored smooth surface reservoir end, approximately 180 mm in length and 52 mm in width (Type 1, Style 2, Class A) rubber contraceptive device, lubricated with Nonoxynol-9 and silicone. This device is a Class II medical device covered by K901112 and currently sold in interstate commerce under the trade name Lifestyle®

The applicant has received prior authorization to produce medical devices for interstate commerce before. This device was granted pursuant to 21 CFR 800 *et seq.* a 510(k) number K963319 and K963321 for the basic latex condom covered in this application. This device is also substantially equivalent, except the applicant device contains color.

Class of Device: Class II, Condom (rubber) Contraceptive - 85HIS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lillie C. Thomas, M.S.
Director of Quality Assurance
Custom Services International, Inc.
3111 West Post Road
Las Vegas, Nevada 89118

Re: K972427
InnerWear™, Jimmy-O Raincoat™, Raincoat™, Jasmine™, Drink®
Dated: June 26, 1997
Received: June 27, 1997
Regulatory class: II
21 CFR §884.5300/Product code: 85 HIS

AUG 20 1997

Dear Ms. Thomas:

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 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 requirement, 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) 594-4613. 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 Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K972427

Device Name: **Condom (rubber) Contraceptive 85-HIS**

Indications for Use:

Nonlubricated rubber male condom for use as a contraceptive and prophylactic.

Date Submitted: June 26, 1997

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Nathing

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972427

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