K972428

510(k) Summary Notification

Submitter:	**Custom Services International, Inc.** 3111 Post Rd. Las Vegas, NV 89118
Telephone Number:	(702) 897-1789 AUG 25 1997
Contact:	**Lillie C. Thomas, M.S.** Executive 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) rubber contraceptive device, lubricated with silicone or nonlubricated, **extra strength and colored**.
Trade Names:	ExtraWear™, Gentlemen's Choice™
Equivalent Device:	Custom Services International Inc. Application K970767 (lubricated) and K970792 (nonlubricated) found to be substantially equivalent on June 2, 1997 (Type 1, Style 2, Class A) rubber contraceptive device, lubricated with silicone or nonlubricated, tested to a higher quality standard for added strength and colored.
Class of Device:	Class II, Condom (rubber) Contraceptive - 85HIS

Description of Device Covered by this Submission

The device which is the subject of this application is a latex rubber condom (Class II medical device defined as "Condom (rubber) Contraceptive 85-HIS") and is defined by ASTM 3492-93 as a Type I, Style 2, Class A rubber condom, and further defined by ISO 4074-6 (currently under revision). The device which is defined by these standards can be lubricated or nonlubricated, and for the purposes of selection for labeling as "extra strength" is tested in the strength categories to a higher standard (See **Exhibit A** in K970767 and K970792 as well as **Exhibit 1**) with added FDA certified color. The purpose of this medical device is for the prevention of pregnancy and the protection against sexually transmitted diseases, including HIV.

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: K972428
ExtraWear™, Gentlemen's Choice™
Dated: June 26, 1997
Received: June 27, 1997
Regulatory class: II
21 CFR §884.5300/Product code: 85 HIS

AUG 25 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:

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

Indications for Use:

Extra Strength lubricated rubber male condom for use as a contraceptive and prophylactic.

Additional Statement: "Laboratory tests of physical properties show the ExtraWear condom is stronger than the InnerWear condom. However, the breakage rate during sex has not been tested."

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 D Mathis

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972428

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

510(k) Number:

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

Indications for Use:

Extra strength nonlubricated rubber male condom for use as a contraceptive and prophylactic.

Additional Statement: "Laboratory tests of physical properties show the ExtraWear condom is stronger than the InnerWear condom. However, the breakage rate during sex has not been tested."

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)

Peter R Salber
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K97248

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