K972430

SEP 10 1997

#1011

510(k) Summary Notification

Submitter:	**Custom Services International, Inc.** 3111 Post Rd. Las Vegas, NV 89118
Telephone Number:	(702) 897-1789
Contact:	**Lillie C. Thomas, M.S.** Executive Director of Quality Assurance
Registration Number:	**2951584**
Date Submitted:	June 25, 1977
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 and the active ingredient Nonoxynol-9 spermicide, **extra strength and colored.**
Trade Names:	ExtraWear™, Gentlemen's Choice™
Equivalent Device:	Custom Services International Inc. Application K970791 found to be substantially equivalent on June __, 1997 (Type 1, Style 2, Class A) rubber contraceptive device, lubricated with Nonoxynol-9 and silicone, tested to a higher quality standard for added strength and colored.
Class of Device:	Class II, Condom (rubber) Contraceptive - 85LTZ

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-LTZ") 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 is also lubricated, contains a spermicide (Nonoxynol-9) 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 K970791 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. The Food and Drug Administration has offered regulatory guidance concerning condoms containing spermicide. The FDA tests condoms entering the United States prior to entry into interstate commerce to verify, if labeled as containing spermicide, that each device contain a minimum amount of 25 mg. of

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Nonoxynol-9 spermicide.[1,2] The spermicide, Nonoxynol-9 reduces the number of active sperm, thereby decreasing the risk of pregnancy if erection is lost and some semen spill outside the condom. The amount of this decreased risk has not been established.[3] (See **Section I: Material Safety and Effectiveness**).

The Food and Drug Administration has not formally promulgated rules concerning the requirements of the applicant's medical device. Instead, the FDA has sought voluntary compliance of all condom manufacturers with the performance requirements of ASTM 3492-93 for physical properties and leakage standards and ISO 4074-6 (currently under revision) for air burst standards and testing. The applicant has instituted these standards as the basis for its established manufacturing practice for all of its devices. For the device covered by this application, the applicant has added pigment with FDA certified colors to a device with a higher testing standard in the strength categories (tensile, breaking force, air burst, thickness, and added water requirements for leakage testing) found to be "substantially equivalent" pursuant to application K970791.The applicant device has been tested and has met or exceeded all the voluntary standards concerning the applicant medical device, at the time of acceptance from manufacturing and through accelerated aging, it can be projected to meet the voluntary standards at the end of the shelf life. The applicant has designed its operating procedures to verify and assure that the applicant's device meets or exceeds the voluntary standards for the entire projected shelf life of the applicant device. This verification of the operating procedures is to assure process validation for the entire period, is designed to comply with the spirit of the general requirement for all medical devices which enter interstate commerce. The verification is specifically designed to demonstrate that the applicant's medical device be safe and effective for the purpose for which is intended.[4]

In essence, the FDA requires that the applicant device not be "misbranded" or "adulterated", as those terms are defined in the federal regulations. The final requirements, based on the voluntary standards requested by and used as the test standard by the FDA, and the regulations concerning

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[1] The applicant's device meets the established definition found in 21 CFR 884.5310. Nonoxynol-9 is the recognized spermicide that is to be used in male condoms by regulation.

[2] The applicant has instituted a Standard Operating Procedure SOP#2-021 which requires an independent insertion of the Nonoxynol-9 in the amount of 30 mg. ± 5 mg. to assure the proper amount of the active ingredient is present in the applicant medical device. See **Exhibit C** in K970791

[3] The applicant has included on its exterior packaging (See **Section III: Packaging and Marketing Materials**) this regulatory language as required by FDA.

[4] The applicant instituted accelerated shelf life aging as a routine good manufacturing practice prior to the issuance of the of the proposed FDA rule published in the Federal Register in May, 1996.

packaging for all medical devices including the applicant device are as follows: To avoid misbranding, the applicant device should be properly labeled and instructions properly provided (See **Section III: Packaging and Marketing Literature**)[5]. To avoid adulteration, the applicant device should meet the following minimum requirements at the end of the device shelf life: air burst testing per ISO 4074-6 (under revision) of 1 mPa to 20 liters of air at an AQL of 1.5; no leakage detected at an AQL level of 0.4; tensile strength of not less than 15 mPa; minimum breaking force of 18 N.; and minimum elongation of 625%. (For further substantive detail see **Section II: Quality Assurance and Process Validation**). The strength standards (tensile, breaking force, thickness, and air burst) have been increased by the applicant to justify the addition of the term "extra strength" to the device labeling. For the purposes of this application, the definition of "extra strength" will be identical to the definition provided in application K970791[6] and the device discussed in this application will meet all of the mechanical requirements outlined for the device covered by K970791. (See **Exhibit A to K970791** and **Exhibit 1**).

Statement of Intended Use and Function

The device covered by this application is defined by ASTM 3492-93 a smooth surface, reservoir tip. latex rubber condom (Type 1, Style 2, Class A), and by the Food and Drug Administration as Class II. Condom (rubber) Contraceptive - 85LTZ with a lubricant that contains the active ingredient Nonoxynol-9 and FDA certified pigments for coloration for the purpose of birth control and protection against sexually transmitted diseases, including HIV. *There is no difference in composition, intended use, or contra indications between the device covered by this application and the Equivalent Device covered by the applicant's equivalent device K970791. The device covered by this application merely adds certified FDA pigments to the device covered by K970791.*

The device covered by this application is substantially equivalent to the predicate device manufactured by the applicant and covered by the 510(k) application K970791. The device covered by this application and the predicate device are both made of latex rubber formulated and

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[5] For the purposes of this application, the applicant proposes to add the term "extra strength" to the device labeling covered by this application.

[6] The applicant is proposed the following definition for "extra strength": In all categories of physical testing which demonstrate strength, the applicant device is to meet a standard that is at a minimum 10% greater than the applicant accepted standard, and in the categories which define mechanical strength, the standard is set higher. Tensile strength is the requirement most closely related with the strength of the applicant's medical device. This requirement has been increased significantly (greater than 20%). The applicant submits that it meets the proposed definition established for "extra strength". In a review of the competitive devices (Trojan® and Lifestyles®) published literature on the "extra strength" version of their respective devices it appears that the term applies to the thickness of the device , not the attributes of strength. The applicant proposes to make "extra strength" reflective of all of the parameters affecting strength.

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tested to an acceptable ISO standard, lubricated with silicone containing a recognized spermicide, Nonoxynol-9, voluntarily complying with ISO 4074-6 and ASTM 3492-93 for air burst properties and physical respectively. Both the predicate device and the applicant device are fully covered within the scope of the definition provided for device by the FDA in 21 CFR 884.5310. Per FDA regulatory guidance, condoms containing Nonoxynol-9 must contain a minimum of 25 mg. of the active ingredient. The applicant medical device, in order to assure full compliance with the federal regulations concerning the use of the active ingredient, adds in addition to the silicone lubricant a minimum of 25 mg. of Nonoxynol-9. Both the applicant device and the predicate device meet all of the requirements established by ASTM 3492-93 and ISO 4074-6 (currently under revision) as required by the regulatory policy established for this medical device by the Food and Drug Administration. There is no difference in physical composition, chemical composition, intended usage, or contra indications of use between the applicant device covered by this application and the predicate device other than the addition of FDA certified color. The applicant proposes to add FDA certified color to the applicant device differentiating it from the predicate device covered by K970791.

Substantial Equivalence Testing

The general requirement applicable to the applicant device established by Federal regulations is that a medical device be safe and effective for the purpose for which it is intended. The applicant device is a Male Condom (Rubber) Contraceptive, 85 LTZ, further defined by ASTM 3492-93 as a Type 1, Style 2, Class A condom, containing FDA colorant, lubricated with silicone and containing the spermicide Nonoxynol-9[7]. Pursuant to the standard established by ASTM 3492-93, the applicant medical device is a natural latex condom, smooth surface, colored with an FDA certified pigment, with a reservoir tip and silicone lubrication containing the spermicide Nonoxynol-9, U.S.P. The size of the medical device is defined by ASTM 3492-93. It is 180 mm ± 20 mm in length, 52 mm ± 2 mm in width, .05 mm in thickness at a minimum, meeting all standards established by the predicate application K970791. These specifications are established by ASTM 3492-93. ISO 4074-6, while also voluntary for air burst testing, regulatory policy has made air burst testing mandatory to this standard for condom manufacturers, although this standard is currently under revision. These standards must be complied with as a matter of practice, and are the standards used by the FDA for auditing the quality of the substantially equivalent device. Documentation that the applicant device complies with or exceeds the voluntary standards, under these conditions, would be sufficient to prove that the applicant device is substantially equivalent to the predicate device. The purpose of this application is to add FDA certified color pigments to the predicate device covered by K970791 thereby adding color. The strength parameters remain the same. The addition of color to the predicate device will not affect consumer use or safety, as the mechanical use is unaffected, and the colorant is approved for

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[7] The spermicide Nonoxynol-9 is a recognized spermicide for contraceptive devices. The active ingredient used in the applicant medical device is Nonoxynol-9, U.S.P. which is the best grade of the spermicide meeting all of the standards established by the U.S. Pharmacopeia.

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direct food contact, a form a contact longer and more direct than that proposed by the applicant.[8] (See **Section I: Material Safety and Effectiveness** and **Section II: Quality Assurance and Process Validation**) Compliance with the standards is sufficient to avoid "adulteration" as that term is defined by Federal regulations and to justify the addition of "extra strength" and "colored" to the device label. (See **Section III: Packaging and Marketing Literature**)

The applicant's device covered by application K970791 is the device to which the applicant device is "substantially equivalent" as that term is defined in Federal regulations. The purpose of this application is to add color to a condom meeting increased standards to which the term "extra strength" is added to the labeling. Colors are recognized as a variation in the device covered by this application in ASTM 3492-93. In the context of ASTM 3492-93, color is not to affect the structural requirements for the medical device. The device is defined by ASTM 3492-93 and ISO 4074-6 a Type I, Style 2, Class A colored condom lubricated with silicone and containing the spermicide Nonoxynol-9. This "substantially equivalent" device to the applicant device has complied with the 510(k) procedure established by the FDA.

The applicant, in order to demonstrate substantial equivalence of the device covered by this application, has assumed that predicate device is lawfully marketed. The predicate device to which the applicant device claims substantial equivalency, therefore is also assumed to be in full compliance with the voluntary standards established ASTM 3492-93 and ISO 4074-6 (currently under revision), as required by the applicable regulatory guidance provided by the FDA. The applicant device has been tested using both "in process" samples and samples which were "aged" according to the requirements set forth in ASTM 3492-93 (6.2.2) for process challenge testing. The testing process was designed to demonstrate that the applicant medical device meets or exceeds all voluntary requirements established for the device as delineated in the regulatory guidance for the applicant device at the beginning and the end of the projected shelf life for the applicant device. The compliance with all of the voluntary requirements promulgated by ASTM 3492-93 and ISO 4074-6 (under revision) and as audited by the FDA in the regulatory guidance concerning the applicant medical device will by definition demonstrate substantial equivalence, as the predicate device by law must be audited to be in compliance with these same requirements.

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[8] See 21 CFR 177.2600 (c)(3) "Substances that by regulation in parts 170 through 189 of this chapter may be safely used in rubber articles, subject to the provisions of such regulation." The applicant is using items which have been approved pursuant to 21 CFR 178 et seq.

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Summary of Nonclinical Testing

The applicant device is identical in materials to the substantially equivalent medical device[9] with the addition of FDA certified color[10] approved for long term food contact in polymers, a level of contact substantially higher than that proposed by the applicant. The applicant has established the following protocol to validate the production and testing process under which the applicant medical device is manufactured. The established manufacturing process defined by the Good Manufacturing Procedures adopted and implemented by the applicant are designed to assure the consumers of the applicant medical device a consistently safe and effective medical device for its intended purpose as required by the applicable federal regulations. The summary of the protocol developed for the purpose of demonstrating substantial equivalence to the predicate device and compliance with the applicable regulations is as follows:

1. Production samples were collected over a period of ten 8 hours shifts, spread over multiple days. All samples are independent lots and were collected using this procedure.

2. The samples were divided in half, to provide a set of matched samples which contained an "as manufactured" sample and an "aged" sample which was incubated as outlined in ASTM 3492-93 part 6.2.

3. The results for the paired samples were recorded and the lots were matched.

4. The data was then statistically analyzed to verify that the samples were in compliance with the added quality standards established by the applicant for its extra strength device, and colorfastness verified. Colorfastness testing is designed to demonstrate that the color does not migrate from the device.

5. The natural colored device and the colored device were compared to demonstrate that there was no difference in the mechanical strength and therefore the safety and effectiveness of the device.

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[9] Both the applicant device and the predicate device are made of natural latex rubber, lubricated with silicone and containing the spermicide Nonoxynol-9. The predicate device is marketed as in interstate distribution under InnerWear™.

[10] The applicant has selected pigments from Ciba Corp. which have been through the FDA certification process and can be used in rubber products pursuant to 21 CFR 177.2600 (Red 254, Green 7, and Blue 15:1) which 21 CFR 178.3297 has certified these colorants for use in polymers, specifically rubber. The level of contact with food, and its resulting human contact through ingestion is a much higher contact with the body than is proposed by the applicant.

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The samples were collected in controlled lots over the course of several production days throughout all shifts. All challenge samples were collected from lots which had been tested according to the applicant's quality assurance procedures which are based on ASTM 3492-93 and ISO 4074-6 and found to be acceptable. The purpose of this method of process verification is to demonstrate that the production process procedures produce consistent medical devices in compliance with the applicable voluntary rules and regulations, thereby demonstrating the consistency of the adherence of the manufacturing facility to the applicant's standard operating procedure. This validation process demonstrates the applicant device's safety and effectiveness for its intended use. These samples were then correlated statistically using cumulative statistical analysis to establish a confidence interval verifying the quality assurance of the device for the purpose of determining the assurance that the medical devices manufactured to the applicant's specification meet or exceed minimum standards established by ASTM 3492-93 and/or ISO 4074 (currently under revision). The applicant has further designed the statistical model used in this application to verify the required AQL levels, consistency of manufacture from shift to shift and longitudinal comparisons to assure that the medical device is consistently safe and effective for its intended purpose over the two year period which is the labeled shelf life of the applicant device. (See **Section II: Quality Assurance and Process Validation**) The statistical method selected for the determination of the safety and effectiveness of applicant device is cumulative testing according to the normal distribution to determine the probability of producing a device which does not comply with the minimum standards for the device, despite the fact the lot code has been tested and passed the quality assurance requirements established by the applicant.

This testing includes Nonoxynol-9 content for shelf life data to prove and assure that the production process produced devices which were in compliance with the required standards for this medical device. The manufacturing facility collected the test data to verify the process, and the tested parameters were independently verified by an FDA certified independent laboratory to assure device integrity.[11] (See **Section II: Quality Assurance and Process Validation**).[12]

The applicant's device covered by K970791 to which the applicant device covered by this application claims substantial equivalence, is equivalent to a predicate device which has been marketed, has an established usage, and is well documented in the medical literature. The basic device (a latex condom with Nonoxynol-9) has been marketed by Schmid Laboratories for an extended period of time and prior to May 28, 1976, with the reclassification of the medical device

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[11] The FDA certified laboratory used by the applicant is Nelson Laboratories, Inc. of Salt Lake City, Utah.

[12] The applicant has initiated a protocol for testing its shelf life of Nonoxynol-9 pursuant to its amendment of its application K963322. A copy of this protocol is attached as **Exhibit B** to K970791 to this application. The shelf life of the applicant device is the same as the predicate device, as there is no change in materials. The effectiveness of the Nonoxynol-9 over the shelf life of the applicant device will also be the same, therefore the results determined from this three year study will also be made part of this device's Master Record.

to include the addition of the Nonoxynol-9 in August, 1982.(This was the predicate device for application K963322, the predicate device for K970791.) The device covered by K970791 is the predicate device for this application. The medical literature concerning the nature of the applicant device and the chemical composition of the device covered by this application, was surveyed and correlated. A summary of the conclusions reached by this material and the associated references are included in Section I of this application. (See **Section I: Material Safety and Effectiveness**). The data detailed in the medical literature is applicable to the applicant device as the applicant device is identical to the predicate device to which substantial equivalence is claimed in all respects. The applicant medical device offers no adverse effects except to those users who are allergic to natural rubber products or Nonoxynol-9 spermicide. A warning concerning this potential reaction is included on the package insert and in all directions for use. (See **Section III: Packaging and Marketing Literature**). The potential adverse reactions of the applicant medical device are identical in all respects to the medical device to which the applicant claims substantial equivalence.

The manufacturing facility for the applicant's medical device is located in the Peoples Republic of China. In April, 1996 the manufacturing facility was inspected for compliance with the Good Manufacturing Practice regulations promulgated by 21 CFR 800 *et seq.* (See **Exhibit C** of K970791) Prior to this inspection, the applicant had prepared and implemented a Good Manufacturing Practice system of Standard Operating Procedures to assure quality and consistent manufacturing of its medical device. The applicant regularly audits for quality assurance and verifies that the manufacturing facility has implemented and followed the manufacturing policies which would assure that the applicant's medical device is produced to the specifications established by the applicant[13]. The applicant audits for compliance with the applicant's good manufacturing practice[14] to assure continuous and complete compliance by the manufacturing facility in order produce medical devices for the applicant which comply with the applicable regulations and good manufacturing practice and thereby yield medical devices which are safe and effective for the purpose intended. This auditing is done via the Self Audit Procedure (See SOP # 2-200M and SOP #2-200C **Exhibit D** of K970791) and routine self inspections by the applicant of its manufacturing facility.

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[13] The applicant conducted its routine GMP internal audit of the manufacturing facility May 18-23, 1997.

[14] See SOP #2-200M and #2-200C in **Exhibit D** to K970791. Self auditing is required by Good Manufacturing Practices, and the reports and testing generated during this process are considered to be the confidential records of the applicant.

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Safety and Effectiveness

The applicant medical device (a colored rubber latex condom lubricated with Nonoxynol-9 spermicide) has a long history of acceptability and use. The base device, (a lubricated rubber condom) has been in use in the United States since the 1930's and a colored condom was in use prior to May 28, 1976. The addition of Nonoxynol-9 was made to the predicate device of K963322 on August 9, 1982.[15] The applicant device, substantially equivalent to the predicate device (K970791), is safe and effective for its established intended use. The intended use of this medical device is for the prevention of pregnancy and protection from sexually transmitted diseases, including HIV. In order for the applicant medical device to be fit for its intended purpose and not be adulterated, it is to meet the mechanical and physical standards established for the device. Particularly the device is to be free of holes and leaks at an AQL level of .4, meaning that leaks are not allowed in more than 4 devices per 1000. The applicant medical device meets the standards required, and is, therefore, effective for its intended purpose. By achieving full compliance with the voluntary standards set in the regulatory guidance for the applicant device, the applicant device is fit for its intended purpose, and is substantially equivalent to the predicate device, as the predicate device must conform to the required regulations as a matter of law in order not to be "misbranded" or "adulterated" and meet all of the requirements for equivalence to K970791. The applicant device merely adds FDA certified pigment to the "extra strength" device found to be "substantially equivalent" in K970791. In order for the applicant device to meet the requirements previously set forth, and to be safe and effective for its intended purpose by definition, the applicant device must (a) be of sufficient mechanical quality to meet the standards required and specified in ASTM 3492-93 and ISO 4076-6 (currently under revision); and (b) be made of materials which are safe for human use in the applicant medical device.

Mechanical Standards

In order for the applicant medical device to meet the mechanical standards, and to be effective for its intended purpose, the applicant device shall [16] (1) be free from holes or leaks; (2) be able to meet all of the required physical standards; (3) be of standard established dimensions required; and (4) be made of materials which are safe for use in the applicant device. The applicant has developed process procedures which produce medical devices that will comply with these standards. The manufacturing practices required by the applicant of the manufacturing facility assures that the applicant device is manufactured to meet and/or exceed the requirements of ASTM 3492-93 and ISO 4074 (currently under revision).

In a recent rule proposal, published in the Federal Register, the FDA has proposed that manufacturers of the device (latex condoms) verify their mechanical standards over the projected shelf life of the medical device. The applicant for process verification and prior to this proposed

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[15] Docket No. 81P-0306 of August 9, 1982 Schmid Laboratories, Inc.

[16] **Food and Drug Administration Compliance Guide** 7124.21

rule [17] for the purposes of demonstration of the mechanical compliance, designed a validation procedure and tested its medical device on an "as manufactured" and "aged" basis using accelerated heat incubation to simulate the full shelf life. This incubation was procedure was incorporated in ASTM 3492-93 6.2.2 (this procedure is also the same as the proposed rule[18]) and via accelerated heat aging would be equivalent to a shelf life of five years.[19] The applicant also has independent laboratory data for colored devices at ambient warehouse temperatures for more than 6 months. The applicant, however, intends to label its medical device for a two year shelf life based on the shelf testing of its supplier of Nonoxynol-9. (See **Exhibit P** of K970791) The applicant intends to further test the shelf period of the Nonoxynol-9 component in actual shelf life studies to determine if the shelf period can be extended (See **Exhibit EE** of K970791). Until such results are available, the applicant will label its device for a shelf life of two years based on its active ingredient, but continue to require that the latex component used in its medical devices comply with a five year standard. This requirement demonstrates that the addition of colorant does not affect the integrity of the device of the applicant. The applicant has verified compliance with these standards by testing its device on a "as manufactured" and "aged" basis assuring with a statistical confidence interval of greater than 95% the applicant's medical device complies with the established mechanical and physical standards. The applicant also verifies that the colorant is colorfast by testing to an AQL level of .5[20]. By complying with the standards established by ASTM 3492-93 and ISO 4074-6 (under revision) which are the accepted standards to assure mechanical and physical effectiveness, the applicant has assured its device is substantially equivalent to the Schmid Laboratories, Inc. device which as a lawfully marketed device, which must comply with the mechanical standards in ASTM 3492-93 and ISO 4074 (under revision). (See **Section II: Quality Assurance and Process Validation**).

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[17] **Federal Register** May 4, 1996, p. 26140

[18] *Id.* ASTM 3492-93 requires incubation for 166 hours ± 2 hours at 70°C. The proposed federal rule is 7 days at 70°C. The difference between the two standards is 2 hours which falls within the variance allowed by the ASTM 3492-93 requirement.

[19] *Id.* "If the latex barrier properties are adequate after undergoing 70°C/7day...the product may be labeled with an expiration date of up to 5 years." p. 26141.

[20] The applicant has elected to maintain a stringent standard for colorfastness to prevent migration of the colorant from the device to the user. The general requirement for this test established is AQL 4.0.

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Component Standards

The other aspect of the safety and effectiveness of the applicant device is that the device be made of materials that are safe for the intended use. The materials used in the applicant device are fit for the intended purpose and are safe for human contact. The applicant device contains three basic functional components: (1) the latex component of which the colorant is an integral part; (2) the silicone lubricant component; and (3) the spermicide (Nonoxynol-9) component. (See **Section I: Material Safety and Effectiveness**). All components are identical to the corresponding components of the substantially equivalent device covered in application K970791 except for the colorant.

Regulatory Requirement

The applicant has designed and initiated the specifications for the applicant device.[21] This application is being filed pursuant to 21 CFR 807.81 (a). Additionally, as the sole distributor of a foreign contract manufacturer, this application is being filed for the applicant device pursuant to 21 CFR 807.81. The applicant has also registered with the FDA as required in 21 CFR 807.20 (a) (1), and will list its devices as required by the same Section upon filing this application. The applicant has developed a set of its own specifications and good manufacturing practice to comply with the GMP requirements of 21 CFR 820.181 et seq.[22] to which the manufacturing facility is required to comply (See SOP #1-002 **Exhibit D1** of K970791)

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[21] See **Exhibit D** in K970791 which contains the applicant specifications, requirements and manufacturing procedures (collectively "GMP" or "SOP") for its medical device.

[22] *Id.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1997

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

Re: K972430
ExtraWear™, Gentlemen's Choice™ with Nonoxynol-9
Dated: June 26, 1997
Received: June 27, 1997
Regulatory class: II
21 CFR §884.5310/Product code: 85 LTZ
21 CFR §884.5300/Product code: 85 HIS

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,

William Yin

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

K972430

510(k) Number:

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

Indications for Use:

Extra strength lubricated rubber male condom with Nonoxynol-9 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."

Additional Statement: This condom contains a latex condom and a spermicidal lubricant. The spermicide, Nonoxynol-9, reduces the number of active sperm, thereby decreasing the risk of pregnancy if you lose your erection before withdrawal and some semen spill outside the condom. However the extent of the decreased risk has not been established. This condom should not be used as a substitute for the combined use of a vaginal spermicide and a condom

Date Submitted: June 25, 1997

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972430

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