510(k) SUMMARY

Submitted by: 807.92(a)(1)

Hollender Sustainable Brands LLC
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Date Prepared: April 21, 2014

Proprietary Name: SUSTAIN Natural Rubber Latex Condoms:Tailored Fit, Ultra Thin, and Comfort Fit 807.92(a)(2)

Common Name: Male Latex Condoms

Classification Name: Condom (21 CFR §884.5300) Code HIS

Predicate Devices: 807.92(a)(3)

Manufacturer	Brand Name	510(k) Number
London International LLC	Ultra Comfort Latex,Rubber Condoms	K980319
London International US Holdings	Durex Colors and Scents, Latex Condoms with Lubricant and Fragrance Additives	K980174

Description of the Device: 807.92(a)(4)

The SUSTAIN Natural Rubber Latex Condoms are made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. These condoms conform to ISO 4074 Natural Rubber Latex Condoms – Requirements and Test Methods, ASTM D3492-08 Standard Specification for Rubber Contraceptives (Male Condom), and ISO 10993 Biological Evaluation of Medical Devices.

Product Smooth Surface – Sustain Tailored Fit
The Sustain Tailored Fit Natural Rubber Latex Condoms are parallel straight walled teat ended with smooth surface, transparent, having a nominal length of 186 ±4 mm, a nominal width of 49±2mm and a nominal thickness of 0.065 ± 0.005mm.

Product Smooth Surface – Sustain Ultra Thin
The Sustain Ultra Thin Natural Rubber Latex Condoms are parallel straight walled teat ended with smooth surface, transparent, having a nominal length of 186 ±4 mm, a nominal width of 52±2 mm and a nominal thickness of 0.055 ± 0.005mm.

Product Smooth Surface – Bulbous – Sustain Comfort Fit
The condoms are bulbous shaped teat ended with smooth surface, transparent, having a nominal length of 186 ±4mm, a nominal width of 52±2mm and a nominal thickness of 0.065 ± 0.005mm.

Intended Use of the Device: 807.92(a)(5)

The Sustain Tailored Fit, Ultra Thin and Comfort Fit condoms are used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

Predicate Product Comparison 807.92(a)(6)

Table 1 Predicate Product Comparisons – Sustain Tailored Fit Natural Rubber Latex Condom

Parameters	Hollender Sustainable Brands LLC	London International LLC	Similarities and Differences
510(k) Number	K131866	K980174	
Intended Use	The Sustain Tailored Fit Natural Rubber Latex Condomsare used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).	A Natural Rubber Latex Condom is intended to be worn over the male penis during acts of vaginal intercourse to aid in the prevention of pregnancy and spread of sexually transmitted infections.	Equivalent
Straight walled teat ended	Yes	Yes	Identical
Nominal length	186 ±4mm	180 ±10mm	Both meet ASTM D3492-08 length specifications
Nominal width	49±2mm	52±2mm	Both meet ASTM D3492-08 width specifications
Nominal thickness	0.065 ± 0.005mm	0.060 – 0.068mm	Both meet ASTM D3492-08 thickness specifications
Smooth surface	Yes	Yes	Identical
Magnesium carbonate and Calcium carbonate dusting powder	Yes	Yes	Identical
Lubricated with Silicone base	Lubricated with Silicone Oil	Lubricated with Silicone Base Zeus Odor Masker and flavors	Predicate uses the identical silicone oil base and incorporates an odor masker and flavors into the lubricant
Transparent	Yes	Colored	Predicate offers different flavors and

			colors

Technological Characteristics Sustain Tailored Fit Natural Rubber Latex Condom 807.92(a)(6)

The Sustain Tailored Fit Natural Rubber Latex Condom and the predicate device (K980174) are made from natural rubber latex, with biocompatible materials and designs in conformance with the requirements of ASTM D 3492-08 Standard Specification for Rubber Contraceptives (Male Condom). Both are cylindrical, straight-walled, teat ended, and use silicone oil as a lubricant. The Sustain Tailored Fit Natural Rubber Latex Condom is transparent and has no flavors or colors, whereas the predicate device (K980174) has flavors and colors. The absence of flavors and colors has no material impact on safety and effectiveness.

Table 2 Predicate Product Comparison Sustain Ultra Thin Natural Rubber Latex Condom

Parameters	Hollender Sustainable Brands LLC	London International LLC	Similarities and Differences
510(k) Number	K131866	K980319	
Intended Use	The Sustain Ultra Thin Natural Rubber Latex Condomsare used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).	A Natural Rubber Latex Condom is intended to be worn over the male penis during acts of vaginal intercourse to aid in the prevention of pregnancy and spread of sexually transmitted infections.	Similar
Parallel teat ended	Yes	Bulbous teat ended	Both meet ASTM D3492-08 specifications
Nominal length	186±4mm	200 ±10mm	Both meet ASTM D3492-08 length specifications
Nominal width	52±2mm	56±2mm	Both meet ASTM D3492-08 width specifications
Nominal thickness	0.055±005 mm	0.055±005 mm	Identical
Smooth surface	Yes	Yes	Identical
Magnesium carbonate and Calcium carbonate dusting powder	Yes	Yes	Identical
Lubricated with Silicone base	Lubricated with Silicone Oil	Lubricated with Silicone Base Zeus Odor Masker	Predicate uses the identical silicone oil base and incorporates an odor masker into the lubricant

Transparent	Yes	Yes	Identical

Technological Characteristics – Sustain Ultra Thin Natural Rubber Latex Condom 807.92(a)(6)

The Sustain Ultra Thin Natural Rubber Latex Condom and the predicate device (K980319) are made from natural rubber latex, with biocompatible materials and designs in conformance with the requirements of ASTM D 3492-08 Standard Specification for Rubber Contraceptives (Male Condom). Both are smooth surface, use identical dusting powder, use silicone oil as a lubricant, and are transparent. The predicate offers a bulbous teat ended feature and the Sustain Ultra Thin Natural Rubber Latex Condom offers a teat ended feature. The difference between the two features has no material impact on the safety and effectiveness as both condoms meet ASTM D 3492-08 Standard Specification for Rubber Contraceptives (Male Condom) recommendations. The differences in the nominal length and nominal width has no material impact on safety and effectiveness as both condoms fall within ASTM D 3492-08 Standard Specification for Rubber Contraceptives (Male Condom) length and width specifications.

Table 3 Predicate Product Comparison Sustain Comfort Fit Natural Rubber Latex Condom

Sustain Comfort Fit Natural Rubber latex Condom Parameters	Hollender Sustainable Brands LLC	London International LLC	Similarities and Differences
510(k) Number	K131866	K980319	
Intended Use	The Sustain Comfort Fit Natural Rubber Latex Condomsare used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).	A Natural Rubber Latex Condom is intended to be worn over the male penis during acts of vaginal intercourse to aid in the prevention of pregnancy and spread of sexually transmitted infections.	Identical
Bulbous shaped teat ended	Yes	Yes	Identical
Nominal length	186±4mm	Length 200±10mm	Both meet ASTM D3492-08 length specifications
Width	The closed end of the condom has a Bulbous with slightly increased width of 57mm – 59mm Nominal width of 52±2mm	The closed end of the condom has a Bulbous with slightly increased width of 59mm– 61mm Nominal width of 56±2mm	Nominal width meets ASTM D3492-08 specifications. Bulbous width is not a safety concern.
Average thickness	0.065 ± 0.005mm	0.055 ± 0.005mm	Both meet ASTM D3492-08 thickness specifications
Smooth surface	SmoothSurface	Smooth Surface	Identical
Magnesium carbonate and Calcium carbonate dusting powder	Yes	Yes	Identical

Lubricated with Silicone base	Lubricated with Silicone Oil	Lubricated with Silicone Base Zeus Odor Masker	Predicate uses the identical silicone oil but incorporates an odor masker into the lubricant
Transparent	Yes	Yes	Identical

Technological Characteristics Sustain Comfort Fit Natural Rubber latex Condom

The Sustain Comfort Fit Natural Rubber Latex Condom and the predicate device (K980319) are made from natural rubber latex, with biocompatible materials and designs in conformance with the requirements of ASTM D 3492-08 Standard Specification for Rubber Contraceptives (Male Condom). Both are cylindrical, bulbous shaped teat ended, smooth surface; use identical dusting powder, use silicone oil as a lubricant, and are transparent. The differences in the nominal length, nominal width and nominal thickness has no material impact on safety and effectiveness as both condoms fall within ASTM D 3492-08 Standard Specification for Rubber Contraceptives (Male Condom) length, width and thickness specifications.

Nonclinical Testing 807.92(b)

The following tests were performed on the Natural Rubber Latex Condoms:

- ASTM D3492-08 Standard Specifications for Rubber Contraceptives (Male Condoms)
- ISO 4074:2002 Natural Rubber Latex Condoms – Requirements and Test Methods
- ISO 10993-5 [2009] Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 [2010] Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization (Penile Irritation)
- ISO 10993-10 [2010] Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization (Primary Irritation)
- ISO 10993-10 [2010] Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization (Vaginal Irritation)
- ISO 10993-10 [2010] Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization (Skin Sensitization Study (GPMT) of Refined Cotton Seed Oil Extract in Guinea Pigs)
- ISO 10993-10 [2010] Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization(Skin Sensitization Study (GPMT) of Normal Saline Extract in Guinea Pigs)
- ISO 10993-11 [2009] Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity

Clinical Testing

No clinical testing was performed.

Conclusion 807.92(b)(3)

The Sustain Tailored Fit, Ultra Thin and Comfort Fit Natural Rubber Latex Condoms are substantially equivalent to the predicate device in indications for use, materials and design. Safety and performance testing to ASTM D 3492-08 Standard Specifications for Rubber Contraceptives (Male Condoms)and ISO 10993 Biological Evaluation of Medical Devices has concluded that the Sustain Tailored Fit, Ultra Thin and Comfort Fit Natural Rubber Latex Condoms are substantially equivalent to the predicate devices (K980174 and K980319) in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 15, 2014

Hollender Sustainable Brands, LLC
% E.J. Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

Re: K131866
Trade/Device Name: SUSTAIN Tailored Fit, Ultra Thin and Comfort Fit Natural Rubber Latex Condoms
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated (Date on orig SE ltr): April 4, 2014
Received (Date on orig SE ltr): April 4, 2014

Dear E.J. Smith,

This letter corrects our substantially equivalent letter of May 1, 2014.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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. 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,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131866

Device Name
SUSTAIN Tailored Fit, Ultra Thin and Comfort Fit Natural Rubber Latex Condoms

Indications for Use *(Describe)*
The Sustain Tailored Fit, Ultra Thin and Comfort Fit condoms are used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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