12/03/2010

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Section 1

In Support of 510(k) K101522 - Ultra Seal Corporation Sterile Lubricating Jelly

510(k) Summary (Amended-Version 3)
Ultra Seal Sterile Lubricating Jelly K101522
I. General Information on Submitter

Company: Ultra Seal Corporation
521 Main Street
New Paltz, N.Y. 12561
Registration Number: 1317759
Contact: James Davis
Executive Vice President, Regulatory Affairs
Telephone: 845-691-8361 ext. 117
Fax: 845-691-8360
Date: July 12, 2010

Manufacturing Site:
Ultra Seal Corporation
521 Main Street
New Paltz, NY 12561
Registration Number: 1317759

Device Class: Class I (reserved)
Trade Name: Ultra Seal Sterile Lubricating Jelly
Common Name: Personal Lubricant
Classification Name: Patient Lubricant
C.F.R. section: 21 CFR section 880.6375
Classification Panel: General Hospital

New Device's Name: Ultra Seal Sterile Lubricating Jelly
Predicated Device(s):
Triad Lubricating Jelly, Manufactured by HP Industries Originally, (K871169)
Sheffield Pharmaceuticals Sterile Lubrigel, Manufactured by Sheffield Pharmaceuticals, Inc. (K073684).

Information supporting claims of substantial equivalence, as defined under the Federal Food Drug and Cosmetic Act, with respect to safety and effectiveness is summarized below. For the convenience of the reviewer, this summary is formatted in accordance with the Agency's final rule, "510(k) Summaries and 510(k) Statements" (21 CFR 807).

K101522

Intended Use:
Ultra Seal Sterile Lubricating Jelly is a medical device intended for medical purposes to lubricate body orifices to facilitate the entry of diagnostic and therapeutic devices and gloved fingers.

Device Description:
Ultra Seal Sterile Lubricating Jelly patient lubricant is a water- based, clear, colorless, odorless, non-sticky, non-greasy, non-staining, nonirritating patient lubricant. It is a water soluble, high viscosity gel-like liquid for use as patient lubricant when a sterile field is required.
Each tube or packet is terminally sterilized by gamma radiation. The product is sterile unless package is opened, damaged, or the seal for the packet product is not intact, with label directions to discard after use.
The product is packaged in a convenient 2 oz., 4.0 oz., and 4.2 oz aluminum tube with a cap and a puncture seal blind, or a 2 oz., 4.0 oz., and 4.2 oz foil laminate tube with a flip top and a peel seal, and 3 and 5 gram laminated film packets, the lamination being paper, polyethylene, foil, polyethylene. All tube configurations contain an aluminum barrier to preserve the product's properties and sterility. Stability has been performed on all tubes and packets and data from 3 months of accelerated studies supports an initial expiration term of 24 months from the date of manufacture. Expiration dating will be confirmed through concurrent room temperature stability studies.
This product is not a contraceptive and does not contain a spermicide.

Regulatory Status:
As per 21CFR, 880.6375, Patient Lubricant is defined as a Class I medical device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. Patient lubricants are not exempt from 510(k) clearance.

Technological Characteristics:
Ultra Seal Sterile Lubricating Jelly formula is proprietary. The product has no exceptional technological characteristics and consists of safe water soluble ingredients commonly used in topical and ingested products and which are similar or the same as those used in similar to PDI (Sterile) Lubricating Jelly, E-Z Lubricating Jelly, and Sheffield Pharmaceuticals Sterile Lubrigel (K073684) currently on the market.

Ultra Seal Sterile Lubricating Jelly contains all GRAS ingredients: Water, Glycerin, Carbomer, Disodium EDTA, and Sodium Hydroxide (for pH adjustment), with Methylparaben and Propylbaraben as preservatives.

Biocompatibility
Biocompatibility Studies on Ultraseal Sterile Lubricating Jelly was conducted by outside laboratories, in compliance with Good Laboratory Practices (GLPs) demonstrated:
In Delayed Contact Dermal Sensitization Test (Buehler Method) the product was considered a non-sensitizer.
In Vitro Cytotoxicity L929 Agar Overlay Test the product meet the requirements for the test.
Primary Dermal Irritation in Rabbits determined that the product is not a dermal irritant.
All ingredients have high LD50s as summarized in the table below which converts the Dermal Toxicity numbers (when available) based on the percent of inclusion in the formulation:
Carbomer >2gm/Kg Rabbit Dermal X 1% inclusion= 200gm of gel/Kg
Methyl Paraben >500 mg/Kg rat subcutaneous X .05% inclusion= 1000 gm of gel/Kg

Propyl Paraben >1.65 gm/Kg mouse subcutaneous X .05% inclusion= 3300 mg of gel/Kg
Disodium EDTA > Not Available
Sodium Hydroxide>Used as a neutralizer to adjust pH to ~6.8-Neutralized

In a worst case scenario, an average person of 70 Kg would have to apply 14 Kg of gel to approach the LD50 of the most dermally-irritating ingredient. The average application of the gel is 3-5 gm or about 0.3% of this amount.

These ingredients are also used in many OTC and prescription oral remedies.

Ultra Seal Sterile Lubricating Jelly is, therefore, safe for its intended use and substantially equivalent to Sheffield Pharmaceuticals Sterile Lubrigel (K073684) currently on the market.

Sterility:
Ultra Seal Sterile Lubricating Jelly is undergoing the Sterility testing validation mandated by FDA, guided by the Association for the Advancement of Medical Instrumentation (AAMI), and detailed in the attached protocol for sterilization of Ultra Seal (Sterile) Lubricating Jelly by Gamma Radiation and generated by Steris Isomedix, Inc.

510(k) INDICATIONS FOR USE FORM
(Replica of FDA Form)

510 (k) Number (if known): K101522
Device Name: Ultra Seal Sterile Lubricating Jelly
Indications for Use:
For lubrication to provide easy insertion of catheters, endoscopes, or gloved fingers into bodily orifices. The device is intended for use on order of a physician.

Non-prescription over-the-counter use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. James D. Davis
Executive Vice President
Ultra Seal Corporation
521 Main Street
New Paltz, New York 12561

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Re: K101522
Trade/Device Name: Ultra Seal Sterile Lubricating Jelly
Regulation Number: 21 CFR 880.6375
Regulation Name: Patient Lubricant
Regulatory Class: I
Product Code: KMJ
Dated: December 7, 2010
Received: December 8, 2010

Dear Mr. Davis:

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.

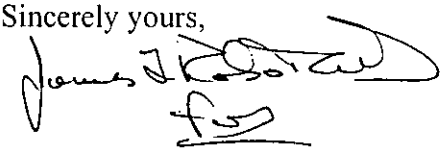
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ULTRA SEAL CORPORATION™ 521 Main Street, New Paltz, NY 12561•1609 845•255•2490 Fax:845•255•3553

Indications for Use

510(k) Number (if known): K101522

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Device Name: Ultra Seal Sterile Lubricating Jelly

Indications for Use: For lubrication to provide easy insertion of catheters, endoscopes, or gloved fingers into bodily orifices.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 12/22/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101522