FEB 6 2006

K052162

510(k) Summary

Applicant: Sheffield Laboratories, Div. of Faria Ltd.
170 Broad Street
New London, Ct. 06320 USA

Signature of Applicant:

Thomas H. Faria - President — Date 8/4/05

Phone: (860) 442-4451
Fax: (860) 442-0356

Contact: Kathleen Hacku
Quality Assurance Manager

Date: July 25, 2005

Manufacturing Site:
Sheffield Laboratories, Div. of Faria Ltd.
170 Broad Street
New London, Ct. 06320 USA

Registration Number: 1210513

Device Class: Class I (reserved)

- Trade Name: Warming LubriGel
- Common Name: Personal Lubricant
- Classification Name: Patient Lubricant
- C.F.R. section: 21 CFR section 880.6375
  Condom: 21 CFR section 884.5300

Classification Panel: Obstetrical/Gynecological

New Device's Name: Sheffield Laboratories Warming LubriGel Personal Lubricant

Predicated Device(s) K-Y Brand Jelly Personal Lubricant
Ortho-McNeil Pharmaceuticals, Inc.
510 (K) No. 5955648

170 Broad Street, New London, CT 06320 USA • (800) 222-1087 • (860) 442-4451 • FAX (860) 442-0356
• Email: general@sheffield-labs.com • Web Site: http://www.sheffield-labs.com

Current Marketed Device: K-Y Brand Warming Jelly
Personal Products Company, Div. of McNeil PPC Inc
510 (K) No. K040164

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).

Intended Use:

Sheffield's Warming LubriGel Personal Lubricant (formula number 3120) is an over-the-counter personal lubricant intended to be used with or without a condom. Sheffield's Warming LubriGel is specially formulated to help supplement the body's own natural lubricating fluids and to reduce friction during sexual intercourse, thereby enhancing sexual intimacy. This lubricant may be safely applied to vaginal, anal or penile tissues for the purpose of lubrication and provides a mild warming sensation when applied to the genital area. This product is compatible with latex condoms.

Device Description:

Warming LubriGel Personal Lubricant is a non-sterile, clear, colorless, odorless, non-sticky, non-greasy, non-staining, non-irritating personal lubricant. It is a water soluble, high viscosity gel-like liquid for use as a personal lubricant. This product provides a gentle warming sensation upon application, designed to meet a consumer's need for a lubricant that does not feel cold. Warming LubriGel is water-soluble and easily rinsed off with water. It is compatible with latex condoms as demonstrated in the Condom Compatibility Testing conducted according to the standards as defined by ASTM D 3492-03.

The product is packaged in a convenient laminate tube with a flip top cap and peel seal.

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. When used as an accessory to a condom, the lubricant is reviewed by the FDA as a Class II Medical Device requiring 510(k) clearance.

Technological Characteristics:

Sheffield's Warming LubriGel has no exceptional technological characteristics and consists mainly of safe water-soluble ingredients. Similar to K-Y Warming Jelly currently on the market, Sheffield's Warming LubriGel contains Propylene Glycol, Polyethylene Glycol, Hydroxypropylcellulose and Lactic Acid.

Summary of Technological Characteristics:

The table below compares the technological characteristics of Sheffield's Warming LubriGel to the currently marketed K-Y Brand Warming Jelly and to the predicated device KY Brand Liquid Personal Lubricant Jelly.

Feature	**Warming LubriGel**	**K-Y Warming Jelly**	**K-Y Liquid Jelly**
Manufacturer	Sheffield Laboratories, Div. Faria Ltd.	Personal Products Company, Div. of McNeil PPC, Inc.	Ortho-McNeil Pharmaceutical, Inc.
Contains Propylene Glycol	yes	yes	no
Contains Polyethylene Glycol	yes	yes	no
Contains Cellulose base jell thickeners	yes	yes	yes
Contains Lactic Acid	yes	yes	no
Contains pH adjuster	yes	yes	yes
Provides Lubrication	yes	yes	yes
Compatible with Latex condoms	yes	yes	yes
Non-sterile	yes	yes	yes
Fragrance Free	yes	yes	yes
Not a contraceptive	yes	yes	yes
Not a spermicide	yes	yes	yes
Container	laminate	laminate	laminate

Substantial Equivalence:

Sheffield's Warming LubriGel has been shown in laboratory tests to be substantially equivalent the currently marketed K-Y Brand Warming Jelly and substantially equivalent to the predicated device K-Y Liquid Personal Lubricant Jelly. All are high viscous gel with the same intended use. Both warming lubricants have exactly the same ingredients, with the same variation in formula ingredients to K-Y Personal Lubricant Jelly. All of these products are sold over-the-counter and are indicated as personal lubricants.

Shuster Laboratories performed a comparative evaluation between K-Y Warming Jelly and Sheffield's Warming LubriGel (formula NS# 3120). Sheffield's LubriGel received a overall rating of 10 in a point rating scale of 1-10 in which 10 is the highest comparative score. The sensory ratings were scored as identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 6 2006

Ms. Kathleen Hacku
QA Manager
Sheffield Laboratories
Div. Faria Limited LLC
170 Broad Street
NEW LONDON CT 06320

Re: K052162
Trade/Device Name: Dr. Sheffield's Warming LubriGel
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: January 11, 2006
Received: January 11, 2006

Dear Ms. Hacku:

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.

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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

510 (k) Number (if known): #K052162

Device Name: Dr. Sheffield's Warming LubriGel

Indications for Use:
Personal Lubricant for penile and vaginal use only (Compatible with latex condoms)

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON AN OTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter-Use ✓
(per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052162