

Summary of Safety and Effectiveness

OCT 29 1998

Just Between Us™ Personal Lubricant & Condom
submitted by
Key West Fragrance & Cosmetic Factory, Inc.
524 Front Street
Key West, FL 33040
Phone: (305) 294-5592
Facsimile: (305) 294-0138

Identification of a Legally Marketed Predicate Devices

The Personal Lubricant used in this convenience kit is substantially equivalent to the following legally manufactured and marketed devices.

- K-Y® Brand Liquid™ Personal Lubricant manufactured by Ortho Pharmaceutical Corporation pursuant to 510(k) K955648
- WonderGel® Personal Liquid Gel manufactured by Lake Consumer Products, Inc. pursuant to 510(k) K903910

Device Description

The Just Between Us™ Personal Lubricant and Condom kit is a non-sterile convenience kit that provides a latex condom and a personal lubricant separately wrapped in the same outer package. The condom is legally manufactured and marketed pursuant to 510(k) K910550 by the London International Corporation. Key West Fragrance & Cosmetic Factory, Inc. will manufacture the personal lubricant. The personal lubricant is non-staining, water-soluble, glycerine and water based lubricant containing Aloe Vera Gel.

Intended Use

The Key West Fragrance & Cosmetic Factory, Inc. Just Between Us™ Personal Lubricant & Condom convenience kit is intended to enhance the comfort and ease of intimate activity. The personal lubricant is compatible with latex condoms.

Summary of Technological Characteristics

The table below compares the technological characteristics of the Just Between Us™ Personal Lubricant to the predicate devices.

Feature	The Just Between Us™	K-Y® Brand Liquid™ Personal Lubricant	WonderGel® Personal Liquid Gel
Manufacturer	Key West Fragrance & Cosmetic Factory, Inc.	Ortho Pharmaceutical Corporation	Lake Consumer Products, Inc.
Contains purified water	Yes	Yes	Yes
Contains glycerine	Yes	Yes	Yes
Contains Aloe Vera Gel	Yes	No	Yes
Contains Methyl-paraben	Yes	Yes	Yes
Labeled Non-staining	Yes	Yes	Yes
Labeled odorless and tasteless	Yes	No	Yes
Container Material	Plastic	Plastic	Plastic
Sterile	No	No	No
Labeled safe with latex condoms	Yes	Yes	Yes

Summary of Performance Data

The Just Between Us™ Personal Lubricant was used to treat condoms that were subsequently tested in accordance with ASTM D 3492-97.⁴ The Just Between Us™ Personal Lubricant and Condom did not have a significant effect on the performance of the condom. The Just Between Us™ Personal Lubricant was tested and found to meet the *in vivo* test requirements of ISO 10993-1, *Biological evaluation of medical devices—Part 1: Guidance on the selection of tests*.

The Just Between Us™ Personal Lubricant and Condom is substantially equivalent to K-Y® Brand Liquid™ Personal Lubricant manufactured by Ortho Pharmaceutical Corporation pursuant to 510(k) K955648 and WonderGel® Personal Liquid Gel manufactured by Lake Consumer Products, Inc. pursuant to 510(k) K903910.

Since the HPBT meets the requirements of the stated standards and embodies technological characteristics essentially identical to the predicate device, we believe the device is

⁴ *Standard Specification for Rubber Contraceptives (Male Condoms)* American Society for Testing and Materials Designation D 3492-97 (1997)

safe and effective and performs as well as or better than the predicate devices. The Just Between Us™ Personal Lubricant and Condom convenience kit will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.



OCT 29 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Joseph R. Liszka
President
Key West Fragrance & Cosmetic Factory, Inc.
524 Front Street
Key West, FL 33040

Re: K982673
Just Between Us™, Personal Lubricant and Condom
Dated: July 24, 1998
Received: July 31, 1998
Regulatory Class: II
21 CFR 884.5300/Procode: 85 HIS

Dear Mr. Liszka:

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 requirements, 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/dsma/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

Indications for Use

510(k) Number (if known): _____

Device Name Just Between Us™ Personal Lubricant & Condom

Indications for Use:

The Key West Fragrance & Cosmetic Factory, Inc. Just Between Us™ Personal Lubricant & Condom convenience kit is intended to enhance the comfort and ease of intimate activity. The personal lubricant is compatible with latex condoms.

If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K992693

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X