K042915

AUG 3 1 2005

10. 510 (K) SUMMARY

Submitted by: O'My Products Inc.
188 Pemberton Avenue
North Vancouver, BC
V7P 2R5
Canada

Contact Person: Rob Logan
Vice President
(604) 990-9700

Proprietary Name: O'My Lubricant

O'My Flavored Lubricants

Common Name: Personal Lubricant

Classification Name: Condom CFR 884.5300

Patient Lubricant CFR 880.6372

Predicate Device:

Class: I

Regulation Number: 21 CFR 880.6375

Regulation Name: Patient Lubricant

K020827 – K-Y Brand Ultra Gel
K021492 – K-Y Brand Warming Liquid Personal Lubricant

Class: II

Regulation Number: Condom 21 CFR 884.5300

Regulation Name: Condom

K021492 – K-Y Brand Warming Liquid Personal Lubricant
K020827 – K-Y Brand Ultra Gel

Description of the Device:

O'My Lubricant and O'My Flavored Lubricants are non-sterile, water-based personal lubricants designed to supplement the body's natural lubrication fluids. The formula is a clear, non-irritating, non-staining, non-greasy natural liquid gel. O'My Lubricant and O'My Flavored Lubricants are compatible with latex condoms as demonstrated in Condom Compatibility Testing.

Intended Use of the Device:

Patient Lubricants are devices intended to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. When used as an accessory to a condom, patient lubricants are deemed Class II Medical Devices.

O'My Lubricant and O'My Flavored Lubricants are principally intended as personal lubricants to supplement the body's own natural lubrication fluids. O'My Lubricants also reduce friction during sexual intercourse enhancing the comfort and ease of intimate sensual activity with or without a latex condom. O'My Lubricant and O'My Flavored Lubricants are also recommended for personal lubrication when dryness causes discomfort.

Technological Characteristics:

O'My Lubricant and O'My Flavored Lubricants contain a proprietary formula. However the products have no exceptional technological characteristics, consisting of water-soluble ingredients similar to other lubricants currently on the US market. Tests have been performed to establish that the product does not compromise safety.

Conclusion:

O'My Lubricant and O'My Flavored Lubricants are substantially equivalent to the predicate devices. The products have the same intended use and similar technological characteristics. No new safety or effectiveness issues have been raised through testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2005

Mr. Rob Logan
Vice President
O'My Products, Inc.
188 Pemberton Avenue
North Vancouver BC V7P 2R5
CANADA

Re: K042915
Trade/Device Name: O'My Natural and O'My Natural Flavored Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: August 22, 2005
Received: August 24, 2005

Dear Mr. Logan:

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

Indications for Use

510(k) Number (if known): **K042915**

Device Name: **O'My Natural Lubricant & O'My Natural Flavored Lubricant**

Indications For Use:

Patient Lubricants are devices intended to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. When used as an accessory to a condom, patient lubricants are deemed Class II Medical Devices.

O'My Lubricant and O'My Flavored Lubricants are principally intended as personal lubricants to supplement the body's own natural lubrication fluids. O'My Lubricants also reduce friction during sexual intercourse enhancing the comfort and ease of intimate sensual activity with or without a latex condom.

O'My Lubricant and O'My Flavored Lubricants are also recommended for personal lubrication when dryness causes discomfort.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042915