(Appendix A)

FEB 17 2006

510(k) Summary of Safety and Effectiveness K053397

Submitter	Personal Products Company Division of McNeil – PPC, Inc. 199 Grandview Road Skillman, NJ 08558
Contact	Nader Fotouhi, Ph.D. Manager, Regulatory Affairs Personal Product Company Division of McNeil – PPC, Inc. 199 Grandview Road Skillman, NJ 08558 Phone: (908) 904-3730 Fax: (908) 904-3748
Date	December 5, 2005
Trade Name	K-Y® Brand SENSUAL MIST™
Common Name	Personal Lubricant
Classification Name	HIS - Condom (21CFR 884.5300) MMS - Patient Lubricant (21CFR 880.6375)
Statement	This modification of the device is substantially equivalent to currently marketed predicate devices, K-Y® Brand Liquid.
Device description	This device is a condom compatible personal lubricant that has been specifically developed to be delivered via a non-aerosol spray pump.

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510(k) Summary of Safety and Effectiveness (Continued)

Intended use	The intended use of this device is as a personal lubricant compatible with latex condom.
Indications statement	This device and predicate devices have similar indications, by being applied to the vaginal area or condom in order to enhance comfort and ease of intimate activity.
Technological characteristics	The device has the same technological characteristics as the currently marketed condom compatible personal lubricants.
Performance data	The results from laboratory testing, pre-clinical evaluations, and human RIPT show that the proposed device performs equivalently to the predicate device. Laboratory test results demonstrated that the proposed device is compatible with the leading commercial brands of latex condoms. Lubricity of the proposed device is comparable to the lubricity of predicate device. The ingredients used in the formulation of the proposed device are generally recognized as safe (GRAS) and the pre-clinical evaluation of the ingredients has determined that they are safe for use in personal lubricant products. The particle size analysis data suggest that any inhalation of the product is not likely to reach the deep lung (i.e., alveolar region). The alveolar region represents the region of the respiratory tract where the most potentially serious health consequences may occur. The human RIPT shows that the proposed device is non-sensitizing.
Conclusion	The proposed device is substantially equivalent to the currently marketed products in technology, intended use, safety, and suitability characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2006

Nader Fotouhi, Ph.D.
Manager, Regulatory Affairs
Personal Products Company
Division of McNeil-PPC, Inc.
199 Grandview Road
SKILLMAN NJ 08558

Re: K053397
Trade/Device Name: K-Y® Brand SENSUAL MIST
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: January 30, 2006
Received: February 2, 2006

Dear Dr. Fotouhi:

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

(Appendix C)

Indications for Use Statement

510(k) Number, if known K053397

Device Name: K-Y® Brand SENSUAL MIST™

Indications for Use:
K-Y® Brand SENSUAL MIST™ is intended as a personal lubricant (for penile and vaginal application) compatible with latex condom.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter Use ✓

Gail A. Bergman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053397

[INFORMATION IN BRACKETS IS CONSIDERED CONFIDENTIAL]