

(Appendix A)

JAN 26 2007

510(k) Summary of Safety and Effectiveness

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	August 28, 2006
Trade Name	K-Y® Brand Touch Massage® 2-in-1 Tingling™
Common Name	Personal Lubricant
Classification Name	HIS - Condom (21CFR 884.5300) MMS - Patient Lubricant (21CFR 880.6375)
Statement	This proposed device is substantially equivalent to currently marketed predicate device, K-Y® Brand ULTRA GEL™.
Device description	This device is a body massage + personal lubricant compatible with latex condom that has been specifically developed produce a tingling sensation and a minty scent.

[INFORMATION IN BRACKETS IS CONSIDERED CONFIDENTIAL]

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. It is may also be used as a body massage product.
Indications statement	This device and predicate device have similar indications, by being applied to the vaginal area or a condom in order to enhance comfort and ease of intimate activity.
Technological characteristics	The proposed device has the same technological characteristics as currently marketed condom compatible personal lubricants.
Performance data	<p>The results from laboratory testing, pre-clinical evaluations and testing, human RIPT and use test 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.</p> <p>The ingredients used in the formulation of the proposed device are generally recognized as safe (GRAS) and the pre-clinical evaluation of ingredients, as well as, testing of prototypes of the proposed device have determined that it is safe for use in personal lubricant products. The human RIPT shows that the proposed device is non-sensitizing.</p>
Conclusion	The proposed device is substantially equivalent to the currently marketed products in technology, intended use, safety, and suitability characteristics.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Nader Fotouhi, Ph.D.
Manager, Regulatory Affairs
Personal Products Company
Division of McNeil-PPC, Inc.
199 Grandview Road
SKILLMAN NJ 08558-9418

JAN 26 2007

Re: K062535

Trade/Device Name: K-Y® Brand Touch Massage® 2-in-1 Tingling™
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulation Number: 21 CFR §880.6375
Regulation Name: Patient lubricant
Regulatory Class: II
Product Code: NUC
Dated: December 14, 2006
Received: December 18, 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.



Protecting and Promoting Public Health

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.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

K062535

Device Name: K-Y® Brand Touch Massage® 2-in-1 Tingling™

Indications for Use:

K-Y® Brand Touch Massage® 2-in-1 Tingling™ is intended as a body massage + 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

David P. Bergman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062535

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