Johnson & Johnson
CONSUMER COMPANIES, Inc.

510(k) SUMMARY

NOV 08 2013

Date Prepared	October 11, 2013
Applicant	Johnson & Johnson Healthcare Products Division of McNEIL-PPC, Inc. 199 Grandview Road Skillman, NJ 08558
Contact Person	Joseph Chmielewski, R.A.C. Associate Director, Regulatory Affairs Johnson & Johnson Consumer Companies, Inc 199 Grandview Road Skillman, NJ 08558 Phone: 908-874-1744 Fax: 908-904-3712 E-mail:jchmiele@its.jnj.com
Proprietary Name	K-Y® Brand Liquibeads®
Common Name	Vaginal Moisturizer / Personal Lubricant
Classification Name	Condom
Classification	Class II
Product Code	NUC
Regulation	21 CFR §884.5300
Predicate Device	K-Y® Brand Intrigue® - K062796
Description	K-Y® Brand Liquibeads® Vaginal Moisturizer is a non-sterile, anhydrous silicone fill mass, encapsulated with a gelatin shell (ovule). The fill mass is composed of a proprietary blend of silicones. The gelatin shell is composed of gelatin NF, glycerin USP, and water USP. The K-Y® Brand Liquibeads® Vaginal Moisturizer is a transparent ovule with a yellowish fill mass. The product is packaged into single

use blister packs with single use disposable applicators, which are then packed into a printed carton.

Intended Use

K-Y® Brand Liquibeads® Vaginal Moisturizer is a personal lubricant for over-the-counter use, for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms. The product is delivered by an applicator.

Technological Characteristics

The subject device, K-Y® Brand Liquibeads® Vaginal Moisturizer, and the predicate device, K-Y® Brand Intrigue® have the same intended use but have different technological characteristics as the subject device encapsulates the personal lubricant in an ovule.

Biocompatibility Review & Testing

The subject device varies from the cleared device only in the fact that it is encapsulated in a gelatin shell and is inserted into the vagina by means of a single-use, disposable applicator. At the concentrations present in the formula, all ingredients are considered safe for human use under the anticipated exposure conditions. In addition, all of the ingredients have been used in legally marketed devices. The use of these ingredients in the subject device raises no new questions of safety or effectiveness.

Studies of vaginal and penile irritation in rabbits were conducted using the fill mass of the subject device. The results showed that the fill mass is non-irritating to genital tissue.

Four additional biocompatibility studies were conducted on the subject device. The test article evaluated in each study consisted of a mixture of the Liquibeads® ovule and 0.9% sodium chloride. The endpoints evaluated included in vitro cytotoxicity, systemic toxicity in mice, contact sensitization in guinea pigs, and vaginal irritation in rabbits. Each study was conducted in accordance with GLP requirements and the applicable ISO 10093 Standard. From the results obtained, it can be concluded that the subject device, K-Y® Brand Liquibeads® Vaginal Moisturizer, is not cytotoxic, does not elicit systemic toxicity, is not a contact sensitizer, and is not irritating to vaginal tissue.

Performance Data –Clinical

A human repeat insult patch test was conducted to evaluate the safety of the fill mass of subject device. The study showed the product did not induce responses indicative of contact sensitization.

Results from an in-home consumer use test show that K-Y® Brand Liquibeads® Vaginal Moisturizer provides vaginal moisturization.

Performance Data –Non Clinical	Condom compatibility testing demonstrates that K-Y® Brand Liquibeads® Vaginal Moisturizer is compatible with natural rubber latex, polyisoprene, and polyurethane condoms. Routine testing demonstrated that the product will remain stable for the labeled shelf-life.
Conclusion	The subject device, K-Y® Brand Liquibeads® Vaginal Moisturizer is substantially equivalent to the predicate device, K-Y® Brand Intrigue®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 8, 2013

Johnson & Johnson Healthcare Products
Lorna-Jane Bremer, M.S., M.B.A., R.A.C.
Director, Regulatory Affairs
Johnson & Johnson Consumer Companies, Inc.
185 Tabor Road
Morris Plains NJ 07950

Re: K122061
Trade/Device Name: K-Y® Brand Liquibeads® Vaginal Moisturizer
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Procode: NUC
Dated: November 4, 2013
Received: November 5, 2013

Dear Lorna-Jane Bremer,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122061

Device Name: K-Y® Brand Liquibeads® Vaginal Moisturizer

Indications for Use: K-Y® Brand Liquibeads® Vaginal Moisturizer is a personal lubricant for over-the-counter use, for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms. The product is delivered by an applicator.

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

Benjamin R. Fisher -S
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Prescription Use_____ AND/OR Over-the-Counter Use__X__
(Per 21 CFR §801 Subpart D) *(21 CFR §801 Subpart C)*