JUL - 8 2005

K051668

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (21 CFR 807.92) [21 CFR 807.87(H)]

The Art of Intimacy Response ™ Personal Lubricant

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.87(h), this information serves as a Summary of Safety and Effectiveness for the ***The Art of Intimacy Response*** ™ **Personal Lubricant**

Submitted By:	Goodmark USA, Inc.
Date:	March 8, 2005
Contact Person:	Boston Talbert Project Manager
Proprietary Name:	The Art of Intimacy Response ™
Common Name:	Personal Lubricant
Classification Name:	The General Hospital and Personal Use Device section of the General Medical Devices Panel within the FDA's Center for Medical Device & Radiological Health considers patient lubricants (21 CFR §880.6375, Class I) to be Class II devices when promoted as being compatible for use with condoms (21 CFR §884.5300)
Intended Use:	*The Art of Intimacy Response* ™ Liquid Personal lubricant is principally intended as personal lubricant to supplement the body's natural lubricating fluids, and to enhance the ease and comfort of intimate sexual activity with or without a latex condom.

Device Description

The Art of Intimacy Response ™ is a non-sterile, aqueous-based personal lubricant designed to supplement the body's own natural lubrication fluids. It is specifically formulated to be a clear, non-irritating, non-greasy, non-staining, high viscosity liquid gel and is compatible for use with or without a latex condom during intimate sexual activity as evidenced by condom compatibility test results per ASTM D 3492. This device is not a contraceptive or spermicide, nor does it contain any such component

Summary of Technological Characteristics

The Art of Intimacy Response ™ Liquid Personal lubricant contains ingredients that are substantially the same as those used in the manufacture of the predicate devices. The ingredients meet specifications defined in the United State Pharmacopoeia (USP) or National Formulary (NF), and are "generally recognized as safe for their intended use" (21 CFR 172.515).

The product was tested by independent laboratories for condom compatibility, biocompatibility and preservative effectiveness. Final results from these tests demonstrate that the device meets established acceptance criteria in accordance with the identified industry standards.

Substantial Equivalence Information:
The intended use, ingredients, and application of the proposed device are substantially equivalent to those of the predicate devices. In determining substantial equivalence, the *Art of Intimacy Response* ™ has been compared with the following legally marketed device to which the Sponsor claims substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2005

Goodmark USA, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, Inc.
1394 25th Street, NW
BUFFALO MN 55313

Re: K051668
Trade/Device Name: ***The Art of Intimacy Response***™ **Personal Lubricant**
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 18, 2005
Received: June 22, 2005

Dear Mr. Job:

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

Page 1 of 1

510(k) Number (if known): K051668

Device Name: ***The Art of Intimacy Response*™ Personal Lubricant**

Indications for Use:

"The Art of Intimacy Response" ™ Liquid Personal lubricant is principally intended as personal lubricant to supplement the body's natural lubricating fluids, and to enhance the ease and comfort of intimate sexual activity with or without a 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 ____
(Per 21 CFR 801.109)

Over-The Counter Use ✓

(Optional Format 1-2-96)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051668