

JAN 13 2005

ATTACHMENT 3

510(k) Summary

K 091467

I. General Information on Submitter

Name: San-Mar Laboratories, Inc.
Address: 4 Warehouse Lane
Elmsford, NY 10523
Telephone: 914.592.3130
Fax: 914.592.5373
Contact Person: Simon Sanders
Date Prepared: June 15, 2004

II. General Information on Device

Name: San-Mar Laboratories Lubricating Jelly
Classification Name: Patient Lubricant

III. Predicate Device

K-Y[®] Lubricating Jelly

IV. Description of Device

The device is a water-based personal lubricant containing chlorhexidine gluconate and methylparaben as preservatives in a vehicle for glucono delta lactone, glycerin, hydroxyethylcellulose, sodium hydroxide, and purified water.

V. Intended Use

The San-Mar Labs Lubricating Jelly is intended for personal lubrication when vaginal dryness causes discomfort and as a lubricant for insertion of rectal thermometers, enemas, douches, and similar types of nozzles.

VI. Technological Characteristics of Device Compared to Predicate Device

The technological characteristics of the San-Mar Labs Lubricating Jelly are identical to those of the predicate device.

VII. Summary of Performance Data

Stability of the San-Mar Labs Lubricating Jelly was confirmed throughout its labeled shelf life (36 months) by a 36 month long-term stability study and a preservative effectiveness test in accordance with USP method <51>.



JAN 13 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Simon Sanders
Director of Quality
San-Mar Labs, Inc.
4 Warehouse Lane
ELMSFORD NY 10523

Re: K041667
Trade/Device Name: San-Mar Laboratories
Lubricating Jelly
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: October 22, 2004
Received: October 28, 2004

Dear Mr. Sanders:

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/dsma/dsmamain.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

Indications for Use

510 (k) Number (if known): K041667

Device Name: KY Type Lubricating Jelly

Indications for Use:

Use Lubricating Jelly to lubricate condoms and for personal lubrication when vaginal dryness causes discomfort. It also eases insertion of rectal thermometers, enemas, and tampons.

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)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041667