CooperSurgical

K063223

510 (k) Summary

JAN 23 2008

Date Prepared [21 CFR 807.92(a)(1)]

Revised January 18, 2008

Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by Joseph Azary (Regulatory / Quality Consultant) on behalf of CooperSurgical, Inc.

Contact Information:

Joseph Azary
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543 Long Hill Avenue
Shelton, CT 06484

Sponsor / Manufacturer:

CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611.

FDA Registration:

CooperSurgical, Inc. is registered with FDA under Establishment Registration# 1216677.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade name: *Wide-Seal Diaphragms including Omniflex Diaphragms and Arcing Diaphragms*

Common / Classification Name: Contraceptive Diaphragm

Classification: Classification of this device would fall under the responsibility of the Division of Obstetrics and Gynecology. Class II, Product Code: HDW, 21 CFR 884.5350

Predicate Device [21 CFR 807.92(a)(3)]

The following predicate device has been identified:

- Ortho McNeil Diaphragm - Preamendment

The Milex Diaphragm has been on the market since 1962 prior to the FDA Medical Device Amendments. The U.S. Patent for the Milex Diaphragm is dated May 29, 1962.

The subject device is substantially equivalent to the predicate device. The main difference is the material composition. The Milex Wide-Seal Diaphragms are composed of Silicone and the Ortho Diaphragms are composed of Natural Rubber.

Description of the Device [21 CFR 807.92(a)(4)]

Summary of the Device / Operation / Characteristics

The Milex Wide-Seal contraceptive diaphragm is a shallow cup with a flexing rim. The diaphragm is composed of silicone.

The diaphragm is placed over the cervix and coated with spermicidal cream or gel to prevent pregnancy.

The diagrams are offered in the following sizes:

- 60mm
- 65mm
- 70mm
- 75mm
- 80mm
- 85mm
- 90mm
- 95mm

The diaphragms are offered in two styles:

- Omniflex (Flat or Coil Style that folds in one place only).
- Arcing (Folds in any place to form an arc or bow for insertion)

Intended Use [21 CFR 807.92(a)(5)]

The subject device is intended to completely cover the cervix and used with spermicide to prevent pregnancy.

Technological Characteristics [21 CFR 807.92(a)(6)]

CooperSurgical Inc. believes that the subject device is substantially equivalent to the predicate device.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subjected to and passed a variety of biocompatibility tests, cleaning validation, and functional / mechanical testing. Over 500,000 Milex silicone Diaphragms have been distributed since the device was introduced in 1962.

Conclusion [21 CFR 807.92(b)(3)]

We believe the differences between the subject device and predicate device are minor and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2008

Mr. Thomas G. Williams
Vice President, Regulatory Affairs
and Business Assurance
CooperSurgical, Inc.
95 Corporate Drive
TRUMBULL CT 06611

Re: K063223
Trade/Device Name: Milex Wide-Seal Contraceptive Diaphragm
Regulation Number: 21 CFR §884.5350
Regulation Name: Contraceptive diaphragm and accessories
Regulatory Class: II
Product Code: HDW
Dated: December 28, 2007
Received: January 2, 2008

Dear Mr. Williams:

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 (PMA), 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

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): K063223

Device Name: Milex Wide-Seal Contraceptive Diaphragm

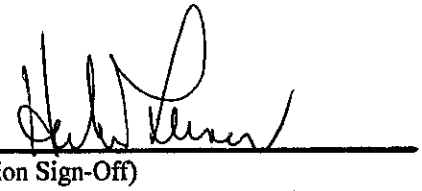
Indications For Use:

Milex Wide-Seal Silicone Diaphragms, in conjunction with an approved spermicidal gel or cream are indicated for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063223