AUG 25 2008

510(k) Summary

Submitter Name:	Johnson & Johnson Produtos Profissionais Ltda. (JJPP)
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Contact Person:	Nancy M.R.B. Lopes M.Sc.
Date Prepared:	19 November 2007
Device Trade Name:	ORTHO® ALL-FLEX® Diaphragm
Common Name	Diaphragm
Classification Name, Number & Product Code:	Contraceptive diaphragm and accessories 884.5350 HDW
Predicate Devices:	Milex Silicone Diaphragm, Cooper Surgical, Inc. ORTHO® ALL-FLEX® Diaphragm (Latex), Ortho Women's Health Global Pharmaceutical Supply Group - A division of Johnson & Johnson
Device Description and Statement of Intended Use	Description: The ORTHO® ALL-FLEX® Diaphragm (arcing spring), is a molded, buff-colored, shallow silicone rubber cup with a flexible rubber covered spring rim. The ORTHO® ALL-FLEX® Diaphragm vaginal diaphragm contains a distortion-free, dual spring-within-a-spring that provides unique arcing action no matter where the rim is compressed. It is appropriate for use not only where ordinary diaphragms are indicated, but also in patients with mild cystocele, rectocele or retroversion. Intended Use: The ORTHO® ALL-FLEX® Diaphragm, in conjunction with an appropriate spermicide, is indicated for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception.

Summary of Technological Characteristics

When inserted into the vagina, the ORTHO® ALL-FLEX® Diaphragm functions as a mechanical barrier that prevents sperm from entering the cervical canal. The spring within the perimeter of the device causes the device to create a seal against the vaginal wall; covering the cervix and preventing sperm from entering the cervical canal. The silicone cup also serves as a repository for spermicide.

A table comparing the ORTHO® ALL-FLEX® Diaphragm to the predicate devices is attached.

Conclusion

The information discussed above demonstrates that the ORTHO® ALL-FLEX® Diaphragm is substantially equivalent to the predicate devices.

Declarations

- This summary includes only information that is also covered in the body of the 510(k).
- This summary does not contain any puffery or unsubstantiated labeling claims.
- This summary does not contain any raw data, i.e., contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.
- This summary does not contain any patient identification information.

Summary of Technical Characteristics

Feature	ORTHO® ALL-FLEX® Diaphragm	ORTHO® ALL-FLEX® Diaphragm	Milex Wide-Seal Silicone Diaphragm
510(k) Number	K080040	N/A Grandfathered	K063223
Manufacturer	Johnson & Johnson Produtos Profissionais Ltda. - A division of Johnson & Johnson	Ortho Women's Health Global Pharmaceutical Supply Group - A division of Johnson & Johnson	Cooper Surgical, Inc.
Classification # & Product Code	884.5350 HDW	884.5350 HDW	884.5350 HDW
Intended Use	The ORTHO® ALL-FLEX® Diaphragm, in conjunction with an appropriate spermicide, is indicated for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception	The ORTHO® ALL-FLEX® Diaphragm, in conjunction with an appropriate spermicide, is indicated for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception	The Milex® Diaphragm, in conjunction with an appropriate spermicide, is indicated for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception
Mode of Action	Mechanical contraceptive barrier	Mechanical contraceptive barrier	Mechanical contraceptive barrier
Reusable	Yes	Yes	Yes
Material of Construction	Medical Grade Silicone	Natural Latex Rubber	Medical Grade Silicone
Standard of Conformity	ISO 8009:2004(E)	ISO 8009:2004(E)	ISO 8009:2004(E)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Johnson & Johnson Produtos Profissionais Ltda.
c/o Mr. William F. Greenrose
President
Qserve America, Inc.
220 River Road
CLAREMONT NH 03743

AUG 25 2008

Re: K080040
Trade/Device Name: Ortho® All-Flex® Diaphragm
Regulation Number: 21 CFR §884.5350
Regulation Name: Contraceptive diaphragm and accessories
Regulatory Class: II
Product Code: HDW
Dated: August 12, 2008
Received: August 12, 2008

Dear Mr. Greenrose:

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 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

4.1 Indications for Use Statement

510(k) Number (if known): K080040

Device Name: ORTHO® ALL-FLEX® Diaphragm

Indications for Use:

The ORTHO® ALL-FLEX® Diaphragm, in conjunction with an appropriate spermicide, is indicated for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception.

(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) **XXX** OR Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080040