DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 26, 2014

Kessel medintin GmbH
Martin Kessel
CEO
Kelsterbacher Str. 28, 64546
Moerfelden-Walldorf, Frankfurt
Germany

Re: K140305
Trade/Device Name: Caya® contoured diaphragm
Regulation Number: 21 CFR§ 884.5350
Regulation Name: Contraceptive diaphragm and accessories
Regulatory Class: II
Product Code: HDW
Dated: July 24, 2014
Received: July 28, 2014

Dear Martin Kessel,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Herbert P. Lerner -S

for
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

4. Indications for Use Statement

510(k) Number (if known):

Device Name: Caya® contoured diaphragm

Indications for Use:

The Caya® contoured diaphragm is indicated for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception. It is recommended for use with a contraceptive gel.

Prescription Use __**XXX**__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

510(k) Summary—Revised

Submitter Name
Kessel medintim GmbH

Submitter Address
Kelsterbacher Str. 28, 64546, Moerfelden-Walldorf, Frankfurt, Germany

Establishment Registration Number
Kessel medintim GmbH will register its establishment and list the Caya®[1] contoured diaphragm prior to initial importation of any devices intended for commercial distribution within the United States.

Phone Number
+49 6105 203 728

Fax Number
+49 6105 455 901

Contact Person
Martin Kessel

Date Prepared
February 5, 2014 (revised July 23, 2014)

Device Trade Name
Caya® contoured diaphragm

Common Name
Diaphragm

Classification Name, Number, and Product Code
Classification Name: Contraceptive diaphragm and accessories (Class II)

Classification Number: 21 CFR §884.5350

Product Code: HDW

Predicate Devices
ORTHO® ALL-FLEX® Diaphragm (silicone), Johnson & Johnson Produtos Profissionais Ltda. – A division of Johnson & Johnson, 510(k) number K080040.

Device Description and Statement of Intended Use
Description: The Caya® contoured diaphragm[2] is a contoured, flexible, single-sized, silicone elastomer cup for covering the cervix that is circumscribed by a rim encapsulating a nylon spring. The Caya® contoured diaphragm has an anatomically shaped spring that has been designed to fit women representing a range of traditional diaphragm sizes.

[1] Caya is a registered trademark of Kessel medintim GmbH of Frankfurt, Germany.
[2] The Caya® contoured diaphragm was known as the SILCS diaphragm throughout design, development, and evaluation.

As with the predicate device, the Caya® contoured diaphragm is inserted by squeezing the rim at the sides to fold the diaphragm into a narrow profile. The Caya® contoured diaphragm has grip dimples along the sides of the rim that provide a tactile cue as to where to squeeze the diaphragm during insertion. The single-size diaphragm was developed and tested as the SILCS diaphragm.

Statement of Intended Use: The Caya® contoured diaphragm is indicated for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception. It is recommended for use with a contraceptive gel.

Summary of Technological Characteristics
When inserted into the vagina, the Caya® contoured 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 contraceptive gel. See Table 5.1 (below) for a comparison of the Caya® contoured diaphragm to its predicate device, the ORTHO® ALL-FLEX® Diaphragm.

Performance Data
The subject device has passed biocompatibility testing in accordance with ISO 10993, performance testing in accordance with ISO 8009, and cleaning validation. Specifically the device has been subjected to and passed the following biocompatibility and performance tests:

Biocompatability testing

- Cytotoxicity Growth Inhibition Test
- Vaginal Irritation Study
- Delayed Type Hypersensitivity
- Genotoxicity, bacterial reverse mutation study
- Inductively Coupled Plasma Investigations
- Gas Chromato-graphic and FTIR Fingerprint Investigations
- ISO intracutaneous study
- Mouse peripheral blood microcutaneous study
- Genotoxicity, mouse lymphoma
- 12-week muscle implant
- Subchronic Systemic Toxicity

Performance testing

- Visual inspection
- Weight
- Kneel-down bending
- Membrane tensile strength and elongation
- Shore A hardness
- Membrane thickness
- Chemical resistance
- Compression Test
- Twist Test

Clinical Testing

In a Phase I post coital study of barrier effectiveness, the SILCS diaphragm[3] used with Nonoynol-9 (N-9) spermicide reduced the average number of progressively motile sperm per high powered field from a baseline of 12.5 to 0, confirming that the SILCS diaphragm would likely perform well in an effectiveness study.

The Phase II/III contraceptive effectiveness study—conducted at six sites in the United States—recruited 450 couples to participate in the study. Couples were randomized to two groups: 300 to SILCS diaphragm used with BufferGel (BG—an investigational lactic-acid based contraceptive gel) and 150 to SILCS diaphragm with N-9 spermicide gel. Healthy, sexually active female volunteers 18–40 years old, at risk for pregnancy, and desiring contraception but at low risk for HIV/STIs, were considered for enrollment. Eligible volunteers were not pregnant, had normal menstrual cycles, were not actively desiring pregnancy and were willing to accept an unknown risk of pregnancy and engage in at least 4 acts of vaginal intercourse per cycle. Participants were followed for at least 190 days and 6 menstrual cycles, and were seen at enrollment and after menstrual cycles 1, 3, and 6. Study outcomes included pregnancy probability, safety, acceptability, diaphragm fit, and ease of use. Results on effectiveness and safety were compared to an historical control group who used the ORTHO® ALL-FLEX® Diaphragm with these gels.

The historical control for the SILCS diaphragm pivotal study was a multi-center contraceptive study conducted by the National Institute for Child Health and Human Development (NICHD). That study demonstrated that BG used with an ORTHO® ALL-FLEX® Diaphragm worked about as well as N-9 with that diaphragm (6-month typical-use cumulative probability of pregnancy rates of 10.1 per 100 women (95% CI 7.1-13.1) and 12.3 (95% CI 7.7-16.9), respectively. [4] The design of the SILCS pivotal study was based on that previous study which was then used in the SILCS historical control analysis to compare the single-size SILCS diaphragm with the ORTHO® ALL-FLEX® Diaphragm on contraceptive effectiveness and safety.

In the SILCS pivotal study, 35 study pregnancies were reported which yielded 6-month Kaplan-Meier cumulative typical-use pregnancy probabilities per 100 women (with 95% confidence intervals) of 10.4 (6.9, 14.0), 9.6 (5.5, 13.6) and 12.5 (5.4, 19.5) for all SILCS users, SILCS with BG and SILCS with N-9, respectively. The rate for all SILCS users was non-inferior to the rate for all users of the ORTHO® ALL-FLEX® Diaphragm, using data from the historical control groups. The observed 6-month cumulative typical-use pregnancy probability was 10.4 per 100 women (95% CI: 6.9, 14.0). The observed 6-cycle cumulative perfect-use probability was 7.9 per 100 women (95% CI: 1.7, 14.0). Extrapolated to 12 months these estimates are for typical use: 17.8 per 100 women (95% CI: 12, 23.6) and for perfect use: 14.0 per 100 women (95% CI: 3.0, 23.6) (See Table 1 (below)).

[3] The Caya® contoured diaphragm was known as the SILCS diaphragm throughout design, development, and evaluation.

[4] Barnhart KT, Rosenberg MJ, MacKay HT, et al. Contraceptive efficacy of a novel spermicidal microbicide used with a diaphragm: a randomized controlled trial. *Obstet Gynecol*. 2007;110(3):577–586.

Table. 5.1. Typical and Perfect Use Pregnancy Probabilities at 6- and 12-months

	Estimated number of pregnancies per 100 women during time period	**95% confidence interval**
6 months		
Typical use	10.4	6.9, 14.0
Perfect use*	7.9	1.7, 14.0
12 months		
Typical use	17.8	12.0, 23.6
Perfect use	14.0	3.0, 23.6

*6-cycle

Conclusion

Differences in technological characteristics between the Caya® contoured diaphragm and the predicate device raise no new safety concerns, and the devices have the same intended use. Results from the pivotal study show that the single-sized Caya diaphragm used with a contraceptive gel provided similar use effectiveness as results from a previously implemented study that evaluated the predicate device (ORTHO® ALL-FLEX® Diaphragm) used with the same contraceptive gels. The single-sized Caya diaphragm has a similar clinical safety profile as the predicate device. The above information demonstrates that the single-sized Caya diaphragm is substantially equivalent to the predicate device.

Table 5.2. Summary comparison of technological characteristics between the single-sized Caya® contoured diaphragm and its predicate.

Attribute	Subject device	Predicate device
Device information		
Trade/Device name	Caya® contoured diaphragm	ORTHO® ALL-FLEX® Diaphragm
510(k) number	K140305	K080040
Manufacturer	Kessel medintim GmbH	Johnson & Johnson Produtos Profissionais Ltda. – A division of Johnson & Johnson
Classification/Product code	21 CFR §884.5350 / HDW	21 CFR §884.5350 / HDW
Similarities		
Indication for use	The Caya® contoured diaphragm is indicated for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception. It is recommended for use with a contraceptive gel.	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.
Mode of action	Mechanical contraceptive barrier	Same
Reusable	Yes	Same
Material (barrier)	Medical-grade silicone	Same
Standard of conformity	ISO 8009:2004(E)	Same
Differences		
Rim shape	Anatomically contoured (arcing spring) in one size (60 to 85 mm)	Circular (arcing spring) in four sizes (65, 70, 75, and 80 mm)
Spring stiffness (relative)	Soft	Stiff
Grip dimples	Present	Not present
Finger removal dome	Present	Not present
Material: spring	Nylon	Metal
Material: color (of silicone)	Violet	Buff