K120107

510(k) Summary

SEP 18 2012

Submitter:

Sckoon Inc.
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Establishment Registration Number 253046

Contact: Satoko Asai
Title: Owner

Date prepared: January 9, 2012
Revision prepared: September 14, 2012

New Device:

Trade Name:	SckoonCup, Size 1 and 2
Common Name:	Menstrual Cup
Classification Name:	Menstrual Cup
Review Panel:	Obstetrics/Gynecology
Regulation Number	21 CFR 884.5400
Product Code:	HHE
Device Class:	II

Predicate Device: MoonCup (K040335)

Predicate Device Information:
MoonCup
Mooncup LLC
One East Main Street, Madison, WI 53701
510(k) Number: K040335

Device Description:

General: SckoonCup is a soft, small silicone menstrual cup that is placed internally in the vagina. The SckoonCup is reusable and it holds menstrual flow instead of absorbing. It may remain in the body up to 12 hours. It is available in two sizes:

* Size 1: Small-Women who have never given birth vaginally; Capacity 23ml
* Size 2: Large-Women who have given birth vaginally; Capacity 30 ml

Material: SckoonCup menstrual cup is manufactured from a soft silicone elastomer. The properties of the silicone elastomer are described in a master file at FDA. The Materials

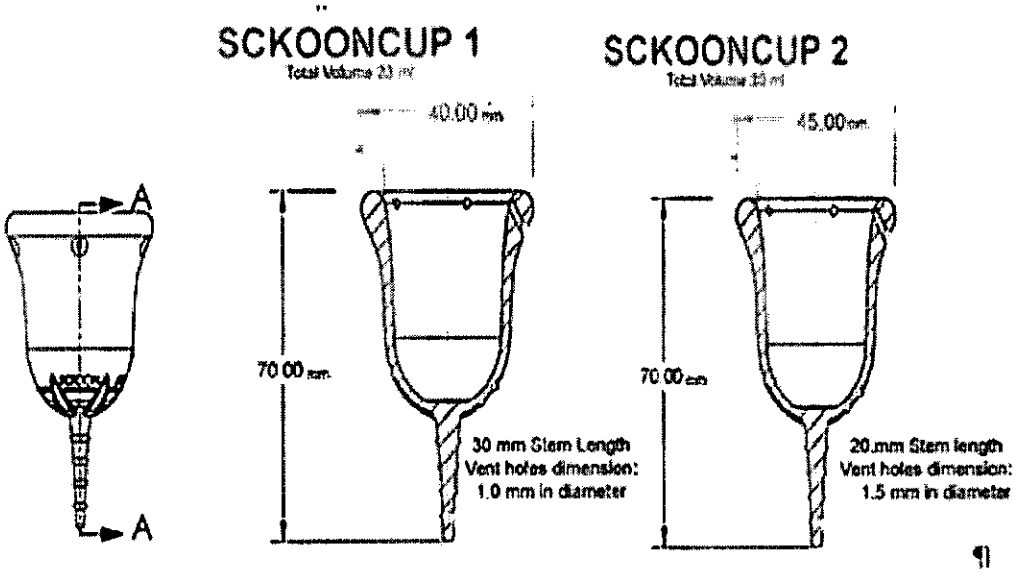
Data Safe Sheet (MDSS) and the Product Specifications Sheet for the silicone were submitted.

Biocompatibility: The silicone elastomer is well characterized chemically and physically and has a long history of safe use in medical devices with human body contact. The master file and the MDSS provide data on the biocompatibility or toxicity testing required according to FDA's memorandum to guidance G95-1. SckoonCup is manufactured in the USA with similar manufacturing methods to the predicate device, in an ISO9001:2008 BSI America Certifiet facilities. SckoonCup has identical use to the predicate device MoonCup (K040335) and same duration of patient contact.

Sterility: SckoonCup is not supplied sterile.

Indications for Use: SckoonCup is a receptacle placed in the vagina to collect blood and cellular debris that is extruded from the uterus via the cervix during menstruation.

Device Drawings:



Comparison to Predicate Devices:

SckoonCup and MoonCup (K040335) are both made of silicone elastomer and the two devices are substantially equivalent in shape, dimensions, material, technological characteristics, and Indications for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Mohamed Elgayar
President
Sckoon, Inc.
2301 Collins Ave #310
MIAMI BEACH FL 33139

SEP 18 2012

Re: K120107
Trade/Device Name: SckoonCup, Size 1 and 2
Regulation Number: 21 CFR§ 884.5400
Regulation Name: Menstrual cup
Regulatory Class: II
Product Code: HHE
Dated: August 24, 2012
Received: September 4, 2012

Dear Mr. Elgayar:

We have reviewed your Section 5.10(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,

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

Indications for Use

510(k) Number (if known): K 120107

Device Name: SckoonCup, Size 1 and 2

Indications for Use:

The SckoonCup is a receptacle placed in the vagina to collect blood and cellular debris that is extruded from the uterus via the cervix during menstruation.

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

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120107