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510(k) SUMMARY

Date of Summary: June 30, 2010

510(k) Submitted by and Primary Contact:

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Device Name: Word Catheter-Silicone Bartholin Gland Balloon Set (final trade name yet to be determined)

Classification Name: Instrument, Manual, Specialized Obstetric-Gynecologic

Panel: Obstetrics/Gynecology

Regulation Number: 21 CFR 884.4530

Regulation Description: Obstetric-gynecologic specialized manual instrument

Device Class: Class II

Product Code: KNA

Indication for Use:

Used for the treatment of abscesses and cysts of the Bartholin gland.

Device Description:

The Word Catheter-Silicone Bartholin Gland Balloon Set is used for treatment of abscesses and cysts of the Bartholin gland. The Word Catheter-Silicone Bartholin Gland Balloon Set is a 3 ml balloon catheter which is 5.5 cm in length and constructed of silicone. The catheter is sold with a 1" 21 gauge needle and a scalpel with a # 11 blade. The blade is used to lance the Bartholin gland cyst/abscess, the syringe with needle is used to inflate the balloon catheter, and the catheter is placed in the cyst or abscess remaining for up to 28 days to allow the duct to re-epithelialize. The devices are provided sterile and are intended for one time use.

Predicate Devices:

510(k) number:	K861385
Current Trade Name:	Word Bartholin Gland Catheter for Cyst and Abscess Drainage

Distributed by:	CooperSurgical Incorporated
510(k) Applicant:	Milex Products Incorporated
510(k) number:	K880497
Current Trade Name:	Word Bartholin Catheter
Distributed by:	Rusch Medical (A Teleflex Medical Company)
510(k) Applicant:	Hoosier Specialties Incorporated

The Cook Word Bartholin Gland Catheter Set is equivalent in technology, materials, and intended use as the Word Bartholin Catheter for Cyst and Abscess Drainage manufactured by CooperSurgical Incorporated. The Cook Word Bartholin Gland Catheter Set is equivalent in technology and intended use as the Word Bartholin Catheter, 10 French manufactured by Rusch (Teleflex Medical) Medical.

Device Comparison

Device	**Word Catheter-Silicone Bartholin Gland Balloon Set**	**Word Bartholin Catheter for Cyst and Abscess Drainage**	**Word Bartholin Catheter, 10 French**
Manufacturer	Cook Urological, Incorporated	CooperSurgical, Incorporated	Rusch Medical (Teleflex Medical)
Intended Use	Used for treatment of abscesses and cysts of the Bartholin Gland	Used following an incision and drainage of a Bartholin cyst or abscess providing immediate relief. However, Bartholin cysts/abscesses have a high rate of recurrence unless the accessory duct is provided to permanently drain the obstructed acini. This can be accomplished by use of the Word Catheter.	Specifically developed for the treatment of Bartholin gland cysts.
Materials	Silicone balloon Silicone Catheter	Silicone balloon Silicone catheter	Latex balloon Silicone Catheter
Dimensions	15 FR with a 3cc balloon and 5.5 cm length	15 FR with a 3cc balloon and 5.5 cm length	10 Fr, 5cm with a 5cc balloon
Components	Syringe with Needle and Scalpel	Syringe with Needle	None known

There are few differences between the Word Catheter-Silicone Bartholin Gland Set offered by Cook Urological, Incorporated, the Word Bartholin Catheter for Cyst and Abscess Drainage offered by CooperSurgical, Incorporated, and the Word Bartholin Catheter, 10 French offered by Rusch Medical. The material used to construct the balloon of the Rusch Balloon is different as it is Latex as opposed to silicone, which is used for the Cook and CooperSurgical Word Balloon. The dimensions of the Rusch balloon catheter are slightly different from the Cook and CooperSurgical balloon catheters, which are identical. The Word Catheter-Silicone Bartholin Gland Set is sold with a syringe with a needle and a scalpel, the Word Bartholin Catheter for Cyst and Abscess Drainage is sold with a syringe with a needle by CooperSurgical, Incorporated. The Word Bartholin Catheter is sold as a stand alone device by Rusch Medical.

Summary of Testing:

The Word Catheter-Silicone Bartholin Gland Balloon Set was tested by the following non-clinical methods to demonstrate that the device is substantially equivalent to the predicate devices in functionality, safety and effectiveness

- Balloon Integrity, Volume, Leak Testing, using modified recommendations from BS EN 1616:1997 (which is nearly identical to ASTM F623-99)
- Balloon Burst Testing, using modified recommendations from BS EN 1616:1997 (which is nearly identical to ASTM F623-99)
- Biocompatibility testing methods as outlined in the ISO 10993 series, conducted using Good Laboratory Practices (GLP).

Biocompatibility, sterility and performance testing were performed in accordance to Food and Drug Administration guidance's and recognized international standards.

Comparison with Predicate Devices:

The results of non-clinical and bench testing indicate that the Word Catheter-Silicone Bartholin Gland Balloon Set is as safe and effective as the predicate devices. The Word Catheter-Silicone Bartholin Gland Balloon Set is similar to the predicate devices in terms of technical characteristics, design, Indications for Use, patient population, performance, and size. The data that was presented for the Word Catheter-Silicone Bartholin Gland Balloon Set prove substantial equivalence to the product devices, prove that the products are safe and effective for their intended use and do not raise any new questions regarding safety and effectiveness.

The Word Catheter-Silicone Bartholin Gland Balloon Set is comparable with respect to intended use to the published predicate device descriptions and meets the requirements for 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Document Mail Center - WO66-G
Silver Spring, MD 20993-0002

Ms. Cindy Foote
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Cook Urological, Incorporated
Cook Women's Health
1100 West Morgan Street
SPENCER IN 47460

MAY - 6 2011

Re: K102141
Trade Name: Word Catheter-Silicone Bartholin Gland Balloon Set
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: KNA
Dated: April 18, 2011
Received: April 19, 2011

Dear Ms. Foote:

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, M.D., Director (Acting)
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): K102141

Device Name: Word Catheter-Silicone Bartholin Gland Balloon Set

Indications for Use: Used for the treatment of abscesses and cysts of the Bartholin gland.

Prescription Use? ___X_____ (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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102141