Special 510(k) Premarket Notification: Uterine Cannulas

CareFusion

APR 21 2014

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

SUBMITTER INFORMATION	
Name	CareFusion 2200 Inc
Address	75 N. Fairway Dr. Vernon Hills, IL 60061
Phone number	(847) 362-8094
Fax number	(312) 949-0272
Establishment Registration Number	1423507
Name of contact person	Jane Weber
Date prepared	18-APR-2014
DEVICE INFORMATION	
Trade or proprietary name	V. Mueller Uterine Cannula
Common or usual name	Uterine Cannula
Classification name	Uterotubal carbon dioxide insufflator and accessories
Classification panel	85 Obstetrics/Gynecology
Regulation	Class II per 21CFR 884.1300, Product code HES
Product Code(s)	GL2360, GL2375, GL2400
Legally marketed device(s) to which equivalence is claimed	V. Mueller Preamendment Uterine Cannulas
Reason for 510(k) submission	Material modification
Device description	The V. Mueller® Uterine Cannula devices are constructed with a stopcock, finger ring control, an elongate shaft and a distal end with a rubber acorn.
Intended use of the device	The proposed devices are intended for use in obstetrical/gynecologic procedures wherein the device is connected to an insufflator on the proximal end. The distal end is inserted through the vagina into the cervix and the uterus and fallopian tubes are insufflated with Carbon Dioxide gas to check for patency.
Indications for use	The Kahn Uterine Trigger Cannula, Jarcho Self-Retaining Uterine Cannula, and Neal Fallopian Cannula are indicated to test the patency (lack of obstruction) of the fallopian tubes by pressurizing the uterus and fallopian tubes and filling them with carbon dioxide gas.

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SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristic	**Predicate Device Preamendment Uterine Cannulas**	**New Device**
Type of Device	Reusable	Reusable
Intended for direct patient contact?	Yes	Yes
Intended for extended use? (more than 24 hrs)	No	No
Cleaning Method	Manual and Ultrasonic	Manual and Ultrasonic
Sterilization Method	Product is sold non-sterile and sterilized by the end user via the following steam sterilization options: • Gravity Displacement • Prevacuum	Product is sold non-sterile and sterilized by the end user via the following steam sterilization options: • Gravity Displacement • Prevacuum
Materials	Stainless Steel Black Silicone Rubber Flexible Tip Cannula: FEP (GL2360 only) Stop cock component • Brass • Nickel	Stainless Steel Black Silicone Rubber Flexible Tip Cannula: FEP(GL2360 only) Stop cock component • Brass • Nickel • Chrome

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

Characteristic	Standard/Test/FDA Guidance	Results Summary
Biocompatibility	ISO 10993-1:2009 / AC 2010	PASS
Functionality	Plating Thickness Analysis	PASS

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

N/A – No clinical tests were conducted for this submission.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The results of the non-clinical tests demonstrate the Uterine Cannulas meet all performance requirements, and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 21, 2014

CareFusion 2200, Inc.
Jane Weber
Regulatory Affairs Manager
75 N. Fairway Drive
Vernon Hills, IL 60061

Re: K140761
Trade/Device Name: V. Mueller Uterine Cannula (Kahn Uterine Trigger Cannula, Jarcho Self-Retaining Uterine Cannula, and Neal Fallopian Cannula)
Regulation Number: 21 CFR§ 884.1300
Regulation Name: Uterotubal carbon dioxide insufflator and accessories
Regulatory Class: II
Product Code: HES
Dated: March 25, 2014
Received: March 26, 2014

Dear Jane Weber,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140761

Device Name
V. Mueller Uterine Cannula (Kahn Uterine Trigger Cannula, Jarcho Self-Retaining Uterine Cannula, and Neal Fallopian Cannula)

Indications for Use *(Describe)*
The Kahn Uterine Trigger Cannula, Jarcho Self-Retaining Uterine Cannula, and Neal Fallopian Cannula are indicated to test the patency (lack of obstruction) of the fallopian tubes by pressurizing the uterus and fallopian tubes and filling them with carbon dioxide gas.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
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