MEDIGROUP, Inc.

MAY 2 1 2012

510(k) Summary

Basic Information

Submitter: Medigroup Inc
14A Stonehill Rd
Oswego IL 60543

Establishment Registration Number: #1450420
Contact: Irene K. Navis
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Date of Submission: January 13, 2012

Device Information

Trade Name:	Faller Trocar
Common Name:	Catheter Tunneling Device
Product Code:	FJS, Accessory
Class:	II

Predicate Devices

K910786	Trocar (Faller Stylet)
K823331	Tunnelor Tool

Product Description

The Faller Trocar is a surgical tool, made of either stainless steel or approved plastic, with a barbed section on one end and a sharp tip on the other end. The device is curved so that the physician using it can follow a tunnel path to lead the catheter from the initial catheter implantation site to the exit-site in an ante-grade manner.

Intended Use

The Faller Trocar is used to create an ante-grade subcutaneous tunnel for a peritoneal dialysis catheter from the initial implantation site to the preferred exit-site. It separates the tissue as it leads the catheter through to the skin exit-site.

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Substantial Equivalence

The new Faller Trocars have the same Indications for Use as the two predicate devices. They are all used to create a subcutaneous tunnel through which to lead the catheter from the initial implantation site through the exit-site. The predicate device Tunnelor® Tool does this in a retro-grade manor, as opposed to an ante-grade manner, but the end result is the same – getting the distal end of the catheter out through the exit-site in the skin.

The new Faller Trocars also have a barbed end to which the catheter is attached. This barbed end is exactly the same as the predicate, Tunnelor® Tool. The new Faller Trocars both have a sharp tip, just as the predicate Covidien's Trocar (Faller Stylet), which is inserted into the initial implantation site to open up the tunnel path through the subcutaneous tissue.

The new Faller Trocars are made of the same materials as the predicate devices, stainless steel like Covidien's Trocar (Faller stylet) and an approved plastic like Medigroup's Tunnelor® Tool. The shape and bend of the new stainless steel Faller Trocar is similar to the predicate Covidien's Trocar (Faller Stylet). The curvature of the new plastic Faller Trocar is similar to the predicate Medigroup's Tunnelor® Tool. The two different shapes give an option to the implanting surgeon to use which one he prefers.

Testing

The barbed ends and the cutting tip were tested in-house with acceptable comparisons between the new Faller Trocars and the two predicate devices. In addition, both of the predicate devices have been used by physicians for twenty years or more. Evaluation of Journal articles and historical data of the predicate devices indicate their safety and effectiveness. Because of the equivalency of the new Faller Trocars to those predicates, the new devices will function as safely and effectively.

Conclusions

The Faller Trocars, either made of stainless steel or an approved plastic, will function as designed and intended. Because of their substantial equivalence to the two predicate devices, they will be as safe and effective as the predicates which have a proven record of more than twenty years of successful use.

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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

Ms. Irene Navis
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MAY 21 2012

Re: K120130
Trade/Device Name: Faller Trocar
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FJS
Dated: May 14, 2012
Received: May 16, 2012

Dear Ms. Navis:

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.

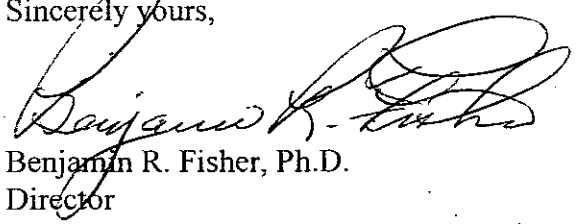
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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): K120130

Device Name: Faller Trocar

Indications for Use: The Faller Trocar is used to create an ante-grade subcutaneous tunnel for a peritoneal dialysis catheter from the initial implantation site to the preferred exit-site. It separates the tissue as it leads the catheter through to the skin exit-site.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K120130