510(k) Summary: K120154

MAR 2 1 2012

Applicant/Sponsor: Catheter Research, Inc.
5610 W. 82nd St.
Indianapolis, IN 46278

Contact Person: John Steen
317-872-0074 x3517

Date: 12/22/2011

Proprietary Name: IUI Catheter

Classification Name: Assisted Reproduction Catheters; CFR 884.6110;
Product Code: MQF

Legally Marketed Devices to Which Substantial Equivalence Is Claimed:

Fertiligent Slow Release IUI Catheter K092579

Device Description: The IUI Catheter is a balloon catheter for intrauterine insemination. The catheter is placed in the uterus and sperm is injected through the catheter in less than several minutes. The IUI Catheter is a packaged, sterile, disposable, flexible, plastic catheter with two lumens, one for inflation of the balloon and one for injection of washed sperm. A balloon inflation syringe is provided with the product.

Intended Use: Delivery of washed sperm into the uterus

The predicate device is intended for the delivery of approximately 1ml of sperm into the uterus over 3 – 4 hours using a controlled release pump.

Summary of Technologies: The IUI Catheter has the identical technologies as the predicate device, IUI catheter component. The IUI Catheter is identical in materials and function to the predicate. Both devices are assembled in the same environment using the same manufacturing and sterilization process.

Non-clinical/Clinical Testing: Biocompatibility, Endotoxins, HSSA testing, sterilization validation, shelf-life, and performance testing.

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Equivalence Summary			
Item	**Predicate**	**Proposed**	**Comments/Discussion**
Component	Mechanical Actuator	Not included	Not part of proposed device; required for Slow Release product, not required for bolus injection IUI.
Component	Insemination Syringe	Not included	Not part of proposed device. Required for Slow Release product due to syringe fit in pump; not required for bolus injection IUI as a sperm-compatible syringe is chosen by the andrology lab.
Component	Leg Strap	Not included	Not part of proposed device; required for Slow Release product, not required for bolus injection IUI.
Component	IUI Catheter	IUI Catheter	Identical: No design, manufacturing, material, sterilization, or packaging differences.
Indication for Use	Delivery of approximately 1 ml of sperm into the uterus over 3-4 hours using a controlled release pump.	Delivery of washed sperm into the uterus.	Proposed device is for standard IUI use, where injection is over a shorter period of time. Comparable use for both products.
Use	3-4 hour insemination	< several minutes	Proposed device is identical to predicate and does not raise any new biocompatibility concerns. The predicate device was cleared for 4 hr sperm contact, whereas the proposed has reduced sperm contact duration, and therefore does not raise any new sperm compatibility concerns. Acceptance criteria are the same for both proposed and predicate devices.
Endotoxin Testing	≤ 20EU/device	≤ 20EU/device	Proposed and predicate devices are the same.

Conclusion: Since both the proposed and predicate catheters are *identical*, we feel that the testing performed on the predicate is sufficient to support the safety and effectiveness of the proposed IUI catheter.

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

John A. Steen, Ph.D.
President
Catheter Research, Inc.
5610 West 82 Street
INDIANAPOLIS IN 46278

MAR 2 1 2012

Re: K120154
Trade/Device Name: IUI Catheter
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted reproduction catheters
Regulatory Class: II
Product Code: MQF
Dated: January 13, 2012
Received: January 19, 2012

Dear Dr. Steen:

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): K120154

Device Name: IUI Catheter

Indications For Use:

Delivery of washed sperm into the uterus.

Prescription Use __X_____ 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 K120154