SECTION 5 (Rev 4) 510(k) Summary K092579

Applicant/Sponsor: Fertiligent Ltd
P.O.B. 73, Migdal HaEmek 23100
ISRAEL

APR - 2 2010

Contact Person: John A. Steen, Ph.D.
317-872-0074 x17

Date: April 2, 2010

Proprietary Name: Fertiligent Slow Release IUI Catheter Kit

Classification Name: Assisted Reproduction Catheters; CFR 884.6110

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

H/S Catheter	K032835

Device Description: The IUI Catheter is a balloon catheter for slow release insemination. The catheter is placed in the uterus and sperm is injected through the catheter. The kit includes a standard BD 3 ml syringe and a mechanical actuator, as well as an ancillary component, a leg strap. Sperm is loaded into the syringe which is attached to the IUI catheter. The syringe is placed in a plastic, spring loaded mechanical actuator to press on the syringe plunger and deliver the sperm over a 3-4 hour period.

Intended Use: The delivery of sperm into the uterus. The predicate device is intended for the delivery of contrast media or saline into the uterus.

Summary of Technologies: The IUI Catheter has the identical technologies as the predicate device. The IUI Catheter is identical in materials and function to CRI's presently marketed product, Cat. No. TMI 1154, without the placement sheath, without the pinch clamp, and with depth marks printed on the catheter shaft.

Non-clinical/Clinical Testing: Biocompatibility, endotoxin, HSSA, sterility validation, mechanical function, and shelf life testing were completed to document safety and effectiveness of this device. In addition a small clinical trial was included in the testing results, and which lent support to the safety and effectiveness of the device. In conclusion, we feel the subject device is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

Fertiligent, Inc.
c/o John A. Steen, Ph.D.
President
Catheter Research, Inc.
5610 W 82nd Street
INDIANAPOLIS IN 46278

APR - 2 2010

Re: K092579
Trade Name: Fertiligent Slow Release IUI Catheter Kit
Regulation Number: 21 CFR §884.6110
Regulation Name: Assisted reproduction catheters
Regulatory Class: II
Product Code: MQF
Dated: March 25, 2010
Received: March 29, 2010

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.

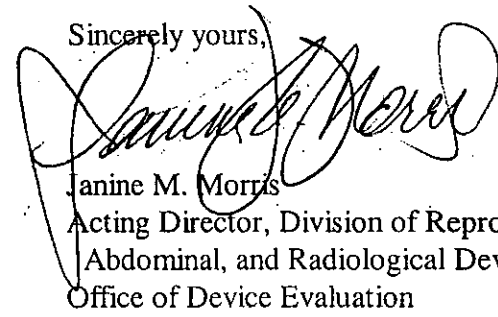
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4 (Rev 3)

Indications for Use

510(k) Number (if known): K092579

Device Name: Fertiligent Slow Release IUI Catheter Kit

Indications For Use: Delivery of approximately 1 ml of sperm into the uterus over 3-4 hours using a controlled release pump.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092579