DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 3, 2015

Fertiligent, Ltd.
% Babacar Diouf
VP of RA and QS
Catheter Research, Inc.
5610 W 82nd Street
Indianapolis, IN 46278

Re: K141666
Trade/Device 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: October 30, 2014
Received: November 5, 2015

Dear Babacar Diouf,

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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 below.

510(k) Number *(if known)* K141666

Device Name
Fertiligent Slow Release IUI Catheter Kit

Indications for Use *(Describe)*
Delivery of approximately 1ml of sperm into the uterus over 3-4 hours using a controlled release pump.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary – K141666

Applicant/Sponsor: Fertiligent Ltd
37 Hashmonaim St.
Ra'anana 43256
Israel

Contact Person: Babacar Diouf
317-872-0074 x3512

Date: February 2, 2015

Proprietary Name: Fertiligent Slow Release IUI Catheter Kit

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

Legally Marketed Devices to Which Substantial Equivalence Is Claimed:

Fertiligent Slow Release IUI Catheter Kit K092579

Device Description: The subject device is a balloon catheter for slow release intrauterine insemination. The catheter is placed in the uterus and sperm is injected through the catheter. The subject device is provided with a standard 3 ml syringe, a mechanical actuator, and a leg strap. Sperm is loaded into the syringe, and the syringe is attached to the IUI catheter. The syringe is placed in the mechanical actuator to deliver the sperm over a 3-4 hour period.

The subject device is identical to the predicate device. The purpose of current 510(k) submission was to remove the Precaution statement from the predicate Instructions for Use stating "Use device only under the supervision of a trained clinician in a medical facility," allowing patients to leave the clinic following device placement and remove and dispose of the device at home or other non-clinical site.

Intended Use: Delivery of approximately 1ml of sperm into the uterus over 3 – 4 hours using a controlled release pump

The subject and predicate device have the same intended use.

Summary of Technologies: The subject device has the identical technologies as the predicate device. The proposed device is identical in materials and function to the predicate device. Both devices are assembled in the same

environment using the same manufacturing and undergo the same sterilization processes.

Non-clinical/Clinical Testing: Biocompatibility, Endotoxins, HSSA testing, sterilization validation, shelf-life, and performance testing were addressed in K092579.

The safety of patient self-removal of the subject device was evaluated as a substudy (n=80) within a multi-center, randomized, open-label, cross-over study comparing the subject device to conventional “bolus” IUI. The study results demonstrated that a typical IUI patient can self-remove the subject device.

Conclusion: The subject device is substantially equivalent to the predicate device.