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

February 26, 2015

Cooper Surgical, Inc.
James Keller
VP Regulatory Affairs & Quality
95 Corporate Drive
Trumbull, CT 06611

Re: K143415
Trade/Device Name: Air Bubble Based Infuser (ABBI™)
Regulation Number: unclassified
Regulation Name: unclassified
Regulatory Class: unclassified
Product Code: LKF
Dated: November 19, 2014
Received: November 28, 2014

Dear James Keller,

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" (21 CFR 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)*

K143415

Device Name
Air Bubble-Based Infuser (ABBI^TM)

Indications for Use *(Describe)*

The ABBI (Air Bubble Based Infuser) is indicated for the following:
- Instillation of a consistent alternating pattern of saline and air as a continuous stream of contrast media into the uterus and fallopian tubes to be used in conjunction with an intrauterine catheter for performance of sono-hysterosalpingogram (SonoHSG).
- Instillation of saline as a continuous stream of contrast media into the uterus to be used in conjunction with an intrauterine catheter for performance of saline infusion sonography (SIS).

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K143415 – 510(k) Summary

Date Prepared: February 24, 2015

510k submitter and Primary Contact: James Keller
VP Regulatory Affairs & Quality
CooperSurgical, Inc.
95 Corporate Dr.
Trumbull, CT 06611
Phone: 203-895-1472
Email: James.Keller@coopersurgical.com

Device Name:

Proprietary Name	Common Name	Classification Name	Product Code
ABBI™	Cannula, Manipulator/Injector, Uterine	Unclassified	LKF

Predicate Information:

FemVue Saline-Air Device (Femasys, Inc.) – K110288

Device Description:

The Air Bubble-Based Infuser (ABBI™) is a dual-barrel syringe that can be connected to an intrauterine infusion catheter to instill a saline-air mixture as contrast media during sono-hysterosalpingogram (Sono HSG) procedures and saline only during hysterosonography (SIS) procedures. The device has a selector valve that allows the user to select infusion of a saline-air mixture for a Sono HSG procedure or saline alone for a SIS procedure. These procedures are used for the evaluation of the fallopian tube(s) selectively and/or the uterus.

The ABBI™ is labeled for use with the H/S Elliptosphere Catheter Set (K013972).

The device is a single use only and provided sterile using an ethylene oxide sterilization method. The device is intended to be used in a healthcare facility or hospital.

Indications for Use:

The ABBI (Air Bubble Based Infuser) is indicated for the following:

- Instillation of a consistent alternating pattern of saline and air as a continuous stream of contrast media into the uterus and fallopian tubes to be used in

conjunction with an intrauterine catheter for performance of sono-hysterosalpingogram (SonoHSG).
- Instillation of saline as a continuous stream of contrast media into the uterus to be used in conjunction with an intrauterine catheter for performance of saline infusion sonography (SIS).

Technological Characteristics:

The technological characteristics of the device are equivalent to the predicate, with the exception of (1) the added feature that allows the ABBI^{TM} to infuse saline only in the performance of SIS (as opposed to only infusing saline-air) and (2) differences in materials between the predicate and the ABBI^{TM}.

Performance Data:

The ABBI^{TM} was tested by the following non-clinical methods to demonstrate substantial equivalence to the predicate device:

- Filling and Infusion Test
- Volume Capacity
- Pressure and Vacuum
- Torque Test
- Steam Deformation Test
- Feature Evaluation
- Summative Usability Assessment
- Multi-Fill Performance Test
- Cadaver - Device Evaluation Study

The protocol and results of the following biocompatibility studies demonstrate that the ABBI^{TM} is non-cytotoxic, non-irritating, and non-sensitizing, respectively.

- Cytotoxicity – MEM Elution (ISO 10993-5:2009)
- Irritation – Vaginal Irritation Study (ISO 10993-10:2010)
- Sensitization – Guinea Pig Maximization (ISO 10993-10:2010)

The results of an accelerated aging study evaluating functional characteristics and package integrity support a 1-year shelf life for the ABBI^{TM}.

Conclusion:

The performance testing demonstrates that the ABBI^{TM} is substantially equivalent to the proposed predicate device.