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

May 24, 2017

Cook Incorporated
Ian Herman
Regulatory Affairs Specialist, China Team
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

Re: K170603
Trade/Device Name: Tao Brush™ I.U.M.C. Endometrial Sampler
Regulation Number: 21 CFR§ 884.1100
Regulation Name: Endometrial Brush
Regulatory Class: II
Product Code: HFE
Dated: February 28, 2017
Received: March 1, 2017

Dear Ian Herman:

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,

Charles Viviano -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)*

K170603

Device Name

Tao Brush™ I.U.M.C. Endometrial Sampler

Indications for Use *(Describe)*

The Tao Brush™ I.U.M.C. Endometrial Sampler is used to obtain endometrial cytological and histological samples.

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.

Tao Brush™ I.U.M.C. Endometrial Sampler

21 CFR §807.92

Date Prepared: May 22, 2017

Submitted By: Ian Herrman
Cook Incorporated
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Phone: (812) 339-2235 x104034
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Device:

Submission:	Traditional 510(k) Premarket Notification
Trade Name:	**Tao Brush™ I.U.M.C. Endometrial Sampler**
Common Name:	Brush, Endometrial
Classification Regulation:	21 CFR §884.1100, Product Code HFE
Device Classification:	Class II
Classification Name:	Endometrial Brush
Classification Panel:	Obstetrics/Gynecology

Predicate Devices:

The predicate device is the Tao Brush™ I.U.M.C. Endometrial Sampler cleared under 510(k) K082066.

Device Description:

The Tao Brush™ I.U.M.C. Endometrial Sampler has a working length of 26.9 centimeters and a 9.3 French outer sheath measuring 21.5 centimeters in length. The outer sheath slides forward and back to cover or expose the bristles of the brush and thus provides protection from contamination when inserting or removing the brush into/from the uterus for the collection of endometrial cell samples. The 9.5 French acrylonitrile butadiene styrene (ABS) ball tip allows for an atraumatic insertion of the device through the cervix and into the uterus. The nylon brush bristles cover a 3.5 centimeter length of the stainless steel wire shaft, near the distal tip, and form a brush diameter of 6 millimeters. Additionally, there are two indicators to aid physicians in the use of The Tao Brush™ I.U.M.C. Endometrial Sampler. The first indicator is a notch on the handle of the device

which allows the physician to track rotations of the brush while collecting endometrial cell samples. The second indicator is a black ink mark located on the outer sheath about 7 centimeters from the distal tip of the device. Through visual observation of this marker, the physician can more accurately gauge how far the brush has entered the uterus. The Tao Brush™ I.U.M.C. Endometrial Sampler is sterilized using ethylene oxide, packaged in a Tyvek® polyethylene peel-open pouch, and has a shelf life of three years. The device is intended for one time use.

Indications for Use:

The Tao Brush™ I.U.M.C. Endometrial Sampler is used to obtain endometrial cytological and histological samples.

Comparison to Predicate Devices:

The predicate device is the Tao Brush™ I.U.M.C. Endometrial Sampler (K082066). The predicate device has not been subject to a design-related recall.

The subject and predicate device have the same intended use but different technological characteristics, namely material composition. The technological differences between the predicate and subject device do not raise any different questions of safety and effectiveness.

Performance Testing:

The following testing was performed in order to demonstrate that the Tao Brush™ I.U.M.C. Endometrial Sampler met applicable design and performance requirements.

- Tensile Strength – Testing shows the tensile force during proper clinical use should not fracture the Tao Brush™ I.U.M.C. Endometrial Sampler materials and bonds. The results showed that the predetermined acceptance criteria were met.

- Torque – Testing shows that torque applied to the device during clinical use should not damage the Tao Brush™ I.U.M.C. Endometrial Sampler. The results showed that the predetermined acceptance criteria were met.

- Bristle Retention – As required in Section 3(ii) of 21 CFR 884.1100, testing was performed to assure bristle adhesion when subjected to forces expected during proper clinical use. The results showed that the predetermined acceptance criteria were met.

- Biocompatibility – Testing demonstrated that the proposed device is non-cytotoxic, non-sensitizing, and non-irritating.

- Shelf life and Packaging Integrity – Testing demonstrates that the package system and materials provide an acceptable sterile barrier as well as a three year device sterility period.

Conclusion:

In conclusion, the results of these tests support a determination of substantial equivalence of the Tao Brush™ I.U.M.C. Endometrial Sampler to the predicate device.