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K112763

POST OAK
INNOVATIONS

## Section 5. 510(k) Summary for MatrixBrush™ Endometrial Sampler

This 510(k) summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c).


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Date Summary Prepared: September 19, 2011

| Device: | | |
|---|---|---|
| | Trade Name: | MatrixBrush™ Endometrial Sampler |
| | Common/Classification Name: | Endometrial brush<br>Product Code HFE |
| | Regulation Number: | 21 CFR § 884.1100 |
| | Classification: | Class II |

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|---|---|
| Predicate Device: | Tao Brush™ I.U.M.C. Endometrial Sampler<br>Cook Urological, Inc.<br>K082066 |
| Device Description: | The MatrixBrush Endometrial Sampler is a sterile, single-use endometrial tissue sampling device. The MatrixBrush shaft is comprised of a spirally twisted stainless steel core covered by plastic with marked gradations. A nylon brush head at the distal end of the device collects a tissue sample and an atraumatic plastic bulb located on the extreme distal end protects the patient from penetration. A moveable plastic sheath overlies the brush head and device shaft. |
| Intended Use: | The MatrixBrush Endometrial Sampler is used to obtain endometrial cells for microscopic examination and/or for microbiology cultures. |
| Summary of Non-Clinical Data Submitted: | As an element of demonstrating safety and effectiveness of the MatrixBrush Endometrial Sampler and substantial equivalence to the predicate device, in vitro testing to evaluate adherence of the bristles and brush head was completed. |
| Safety and Effectiveness: | This premarket notification has demonstrated the differences between the MatrixBrush Endometrial Sampler and predicate device do not raise any questions regarding its safety and effectiveness. The subject and predicate device are substantially equivalent in terms of intended use and technological characteristics. Non-clinical mechanical test results demonstrate the MatrixBrush performance is satisfactory and suitable for its intended use. The MatrixBrush Endometrial Sampler is therefore determined to be substantially equivalent to the referenced predicate device. |

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

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Post Oak Innovations, Inc.
% Ms. Heather Crawford, RAC
Consultant
QA Consulting, Inc.
9433 Bee Caves Road, Building 1, Suite 140
AUSTIN TX 78733

Re: K112763
Trade/Device Name: MatrixBrush™ Endometrial Sampler
Regulation Number: 21 CFR§ 884.1100
Regulation Name: Endometrial brush
Regulatory Class: II
Product Code: HFE
Dated: June 8, 2012
Received: June 11, 2012

Dear Ms. Crawford:

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): K112763

Device Name: MatrixBrush™ Endometrial Sampler

Indications for Use: The MatrixBrush Endometrial Sampler is used to obtain endometrial cells for microscopic examination and/or for microbiology cultures.

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 K112763