510(k) Summary for the FemCerv™ Endocervical Sampler

(Models REF FCV-009, FCV-011, and FCV-013)

DEC 2 0 2012

Date:	December 18, 2012
510(k) Submitter and Primary Contact:	Lisa Peacock Vice President, Regulatory and Clinical Affairs Femasys Inc. 5000 Research Court Suite 100 Suwanee, GA 30024 Tel: 770-500-3910 Fax: 770-500-3980 LPEACOCK@FEMASYS.COM
Device Common Name:	endocervical sampler
FDA Device Classification Name:	endocervical aspirator
Product Code:	PCF
Classification Regulation:	21 CFR 884.1050
Device Class:	2
Panel:	Obstetrics/Gynecology
Indication for Use:	The Femasys FemCerv is a sterile, disposable endocervical sampler indicated for single patient use in obtaining tissue samples from the endocervical canal for histological analysis. Clinical indications include: ▪ further evaluation of an abnormal Pap smear; ▪ cervical lesions extending into the endocervical canal; ▪ undiagnosed uterine bleeding.
Device Description:	The FemCerv Endocervical Sampler (FemCerv) is a sterile, disposable device that collects an endocervical tissue sample for histological evaluation.
Predicate Device:	K060320 FemECC™ Endocervical Curette The FemCerv is substantially equivalent to the predicate in intended use, sample collection method using a single-pass

rotational scraping mode within the endocervical canal, sample transfer method, and in its sterile, disposable, non-metal design.

Summary of Testing:

Final, finished, sterilized FemCerv devices were tested by the following methods for verification of functionality, safety, and effectiveness.

- Bench testing was conducted to evaluate device functionality and integrity over cycle testing of opening and closing the device's sample collection chamber. In addition, the bench testing included simulated use testing in a model of the endocervical canal evaluating insertion capability, sheath opening functionality, rotational functionality, sheath closure, and sample release into a specimen container. A sample set of 29 devices was tested and passed all criteria.
- Shelf life integrity up to 1 year accelerated aging was evaluated using the same test methodology and acceptance criteria in the point above. A sample set of 29 devices was tested and passed all criteria.
- Biocompatibility of components according to ISO 10993 standards: cytotoxicity, irritation, and sensitization was conducted and passed all criteria.
- A clinical study was conducted involving endocervical sampling on subjects prior to scheduled hysterectomy to demonstrate insertion, device opening and closing, and adequate sampling capability based upon a pathologist's evaluation. An 85.7% sample adequacy rate was based on sampling with 7 devices.

Conclusions of Substantial Equivalence Demonstrations:

- FemCerv is substantially equivalent to its proposed predicate device.

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

December 20, 2012

Femasys, Inc.
% Ms. Lisa Peacock
Vice President, Regulatory and Clinical Affairs
5000 Research Court, Suite 100
SUWANEE GA 30024

Re: K122658
Trade/Device Name: FemCerv™ Endocervical Sampler
Regulation Number: 21 CFR§ 884.1050
Regulation Name: Endocervical aspirator
Regulatory Class: II
Product Code: PCF
Dated: December 11, 2012
Received: December 12, 2012

Dear Ms. Peacock:

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,

Herbert R. Lerner

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

Indications for Use

510(k) Number (if known): K122658

Device Name: FemCerv™ Endocervical Sampler
(Models REF FCV-009, FCV-011, and FCV-013)

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The Femasys FemCerv is a sterile, disposable endocervical sampler indicated for single patient use in obtaining tissue samples from the endocervical canal for histological analysis. Clinical indications include:

- further evaluation of an abnormal Pap smear;
- cervical lesions extending into the endocervical canal;
- undiagnosed uterine bleeding.

Prescription Use ___ X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122658