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510(k) Summary for the FemChec™ Pressure Management Device

Date of Summary:	May 31, 2011
510(k) Submitter and Primary Contact:	Lisa Peacock Vice President, Regulatory 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:	contrast media syringe
FDA Device Classification Name:	cannula, manipulator/injector, uterine
Product Code:	LKF
Classification Regulation:	unassigned
Device Class:	unclassified
Panel:	Obstetrics/Gynecology
Indication for Use:	The FemChec™ Pressure Management Device limits the maximum applied pressure while instilling contrast media into the uterus and fallopian tubes. It is to be used in conjunction with an intrauterine catheter for performance of hysterosalpingogram (HSG), such as tubal occlusion confirmation tests in women who have had tubal procedures for permanent female sterilization. The FemChec limits the applied intrauterine pressure to 200 mmHg. The FemChec is provided with a fluid collector, stopcock, and intrauterine catheter for performing the HSG procedure.
Device Description:	The FemChec Pressure Management Device (FemChec) is a pressure-limiting contrast media syringe that is connected to an intrauterine catheter for low-pressure instillation of contrast media during HSG procedures.

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510(k) Summary for the FemChec™ Pressure Management Device

Predicate Devices:

K020954 H/S Elliptosphere Procedure Tray
K792134 Bonchek Vein Distention System, 200 mm Hg
K082725 VasoShield Pressure Controlling Syringe

The FemChec is similar to the H/S Elliptosphere Procedure Tray in that FemChec is a manually operated piston syringe for contrast media instillation, as an accessory to an intrauterine catheter for HSG procedures. Likewise, the predicate tray contains accessories to intrauterine catheters for HSG procedures, including a manually operated piston syringe for contrast media instillation.

The FemChec is similar to the Bonchek Vein Distention System, 200 mm Hg, in that both devices: 1) are syringes for instilling fluids, 2) contain pressure management components, and 3) limit applied pressures to a similar value. The devices differ in the mechanisms of operation and materials of the pressure management component and in their labeled anatomical locations of use, as Bonchek is labeled for use in cardiovascular applications. Although, the clinical use of the Bonchek to limit applied intrauterine pressure during HSG tubal occlusion confirmation tests was reported in the PMA Summary of Safety and Effectiveness Data for the Adiana Permanent Contraception System.

The FemChec is similar to the VasoShield Pressure Controlling Syringe in that both devices: 1) are syringes for instilling fluids, 2) contain pressure management components with similar mechanisms of operation and with similar materials, and 3) limit applied pressures to a similar value. The devices differ in the anatomical locations of use, as VasoShield is indicated for use in cardiovascular applications.

Summary of Testing:

The FemChec was tested by the following non-clinical methods to demonstrate that the device is substantially equivalent to the predicate devices in functionality, safety, and effectiveness:

- fluid instilling function of syringe
- attachment functionality
- single-hand actuation
- pressure testing $\leq$ 200 mm Hg
- biocompatibility of components according to ISO 10993 standards: cytotoxicity, irritation, sensitization, and acute systemic toxicity

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Conclusions of Substantial Equivalence Demonstrations

The FemChec was compared to the predicate H/S Elliptosphere Procedure Tray for the following aspects, and found to have similar technological characteristics and to be substantially equivalent:

- Indications for use, regarding instillation of contrast media during HSG procedures
- Syringe design
- Syringe materials
- Instillation principles of operation
- Sterility

The FemChec was compared to the predicates Bonchek Vein Distention System, 200 mm Hg and the VasoShield Pressure Controlling Syringe for the following aspects, and found to have similar technological characteristics and to be substantially equivalent:

- Indications for use, regarding limiting pressure
- Pressure management components and materials (compared to VasoShield)
- Pressure management principles of operation
- Sterility

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Lisa Peacock
V.P. Regulatory Affairs
Femasys Inc.
5000 Research Court, Ste. 100
SUWANEE GA 30024

OCT 12 2011

Re: K110993
Trade/Device Name: FemChec™ Pressure Management Device
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKF
Dated: September 23, 2011
Received: October 6, 2011

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 P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Femasys Inc.

Indications for Use

510(k) Number (if known): K110993

Device Name: FemChec™ Pressure Management Device

Indications for Use:

The FemChec™ Pressure Management Device limits the maximum applied pressure while instilling contrast media into the uterus and fallopian tubes. It is to be used in conjunction with an intrauterine catheter for performance of hysterosalpingogram (HSG), such as tubal occlusion confirmation tests in women who have had tubal procedures for permanent female sterilization. The FemChec limits the applied intrauterine pressure to 200 mmHg.

The FemChec is provided with a fluid collector, stopcock, and intrauterine catheter for performing the HSG procedure.

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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110993