Femasys Receives FDA 510(k) Clearance for First Low Pressure HSG Device

ATLANTA, Nov. 7, 2011 /PRNewswire/ -- Femasys Inc., an emerging medical device developer of women's healthcare solutions, announced today that it has received 510(k) clearance for the FemChec™ Pressure Management Device, the first device designed for a low pressure HSG as a confirmation test after a permanent sterilization procedure is performed. FemChec utilizes patent-pending technology that limits the applied intrauterine pressure to 200 mmHg, providing confidence to the physician that he/she will not overpressurize while adequately filling the uterine cavity and cornu to obtain the required images. FemChec allows the physician to meet the requirements of the mandatory HSG confirmation test and may reduce improperly performed tests and procedure complications.
Kathy Lee-Sepsick, Femasys' President & CEO, commented, "We have utilized our expertise to respond to the market need for a low pressure HSG test that can be performed with confidence, taking the guesswork out of whether low pressure is truly achieved. The FemChec provides clear benefits to the physician and ultimately the patient as a properly performed low pressure confirmation test is critical to relying on the permanent sterilization procedure long-term."

The FemChec Pressure Management Device will be presented to the gynecologic community in November at the AAGL meeting in Hollywood, Florida. Femasys expects the first devices to begin shipping in the U.S. market in December and is pursuing strategic corporate partnerships for FemChec. The product is expected to contribute to the growing revenue base of Femasys branded products. Earlier this year, Femasys launched the FemVue Saline-Air Device designed to provide gynecologists and their patients with a simple way to evaluate tubal patency in the office with existing ultrasound. The FemVue product has been very well received and is being distributed in the U.S. by Norgenix. The Company is actively seeking other distribution partners for the rest of the world.

About Femasys
Femasys is a privately held corporation committed to advancing women's healthcare with innovative medical devices. The company is continually researching and developing cost-effective new products designed for women, often expanding in-office services that physicians can easily incorporate.

Please visit www.femasys.com [1] and www.femchec.com [2] for additional information.

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