DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Gynétics Medical Products N.V.
% Ms. Grace Holland
Regualtory Consultant
3722 Ave. Sausalito
IRVINE CA 92606

Re: K041237
Trade/Device Name: EchoSampler
Regulation Number: 21 CFR 884.1060
Regulation Name: Endometrial aspirator
Regulatory Class: II
Product Code: 85 HFF
Dated: August 23, 2004
Received: August 25, 2004

Dear Ms. Holland:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K041237

Device Name: EchoSampler

Indications For Use:

The EchoSampler[tm] is a single-use, sterile, disposable curette for:

- Detection of abnormalities of the uterus and endometrium using real-time sonography during injection of sterile saline into the uterine cavity
- Obtaining histological biopsy of the glandular epithelium and superficial chorionic layers of the uterine endometrial wall or sample extraction of uterine menstrual content

for any of the following:

a) Routine screening for early detection of endometrial carcinoma or other precancerous conditions which could make estrogen therapy inadvisable,
b) Evaluation of endometrial tissue response in patients receiving estrogen replacement therapy for menopausal symptoms
c) Endometrial dating and evaluation of uterine pathology associated with infertility, luteal insufficiency, or functional metrorrhagia
d) Identification of specific uterine pathogens by bacterial culturing of uterine samples
e) Inadequate imaging of the endometrium by endovaginal sonography
f) Further evaluation of suspected abnormalities as seen on endovaginal sonography, including focal or diffuse endometrial thickening or debris,
g) Preoperative and postoperative evaluation of the uterine cavity especially with regard to uterine polyps, myomas and cysts
h) Congenital abnormalities and/or anatomic variants of the uterine cavity
i) Infertility and habitual abortion

Prescription Use √ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041237

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