OCT 26 1999

Section 8

510(k) Summary

K992926

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Adena S. Riemer
Associate
EXPERTech Associates, Inc.
100 Main Street, Suite 120
Concord, MA 01742

Tel: (978) 371-0066
Fax: (978) 371-1676

This summary was prepared on August 27, 1999.

2. The name of the RI. MOS. s.r.l. device is GINRAM® Endocic. The common name is curette, and the classification name is Endometrial suction curette.

3. The above device is substantially equivalent to the RI. MOS. s.r.l. device GINRAM® Rampipella, K991895, clearance date August 12, 1999.

4. The RI MOS. s.r.l. curette operates manually by applied vacuum suction and is a sterile single-use disposable device.

5. The device is intended for endometrial sampling for histologic biopsy of the uterine mucosal lining or in patients with cervical stenosis.

6. The technological characteristics are the same or similar to those found with the predicate device.

7. A clinical sampling study was conducted to evaluate Endocic's design for safe and effective collection of endometrial tissue samples by aspiration. Results showed sufficient amount and grade of tissue collection. No perforations occurred and no adverse events were reported. Safety tests were conducted and passed in accordance with the relevant sections of ISO 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 1999

RI. Mos. s.r.l.
c/o Ms. Adena S. Riemer
EXPERTech Associates, Inc.
100 Main Street, Suite 120
Concord, MA 01742

Re: K992926
RI. MOS. s.r.l. GINRAM® Endocic
Dated: August 30, 1999
Received: August 31, 1999
Regulatory Class: II
21 CFR §884.1175/Procode: 85 HHK

Dear Ms. Riemer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K992926

Device Name RI. MOS. s.r.l. GINRAM® Endocic

Indications for Use For endometrial sampling for histologic biopsy of the uterine mucosal lining including post menopausal patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992926