JUL 19 1999

Section 7

K991827

510 (k) Summary

This summary of a 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.(c)

1. The submitter of this premarket notification is:

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

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

This summary was prepared on May 26, 1999.

2. The name of the RI. MOS. s.r.l. devices known as the GINRAM® Cuscovag, Specuvag and Specuvag AS.

3. The above device is substantially equivalent to KleenSpec® Specula marketed by Welch Allyn, K941272.

4. The RI. MOS. s.r.l. speculae line are sterile, single-use, disposable devices.

5. The device is intended as an aid in routine gynecological examinations, including a smoke evacuator model for procedures where such is required.

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

7. 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

JUL 19 1999

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

RE: K991827
GINRAM® speculae – Cuscovag, Specuvag and Specuvag AS
Dated: May 26, 1999
Received: May 28, 1999
Regulatory Class: II
21 CFR §884.4530/Procode: 85 HIB

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

510(k) Number (if known): K991827

Device Name: RI MOS. s.r.l. GINRAM® speculae - Cuscovag, Specuvag and Specuvag AS"

Indications for Use:

The RI MOS. s.r.l. Cuscovag, Specuvag and Specuvag AS devices are used to expose the interior of the vagina. The Cuscovag is indicated as an aid for routine examination in adolescent and geriatric women, the Specuvag as an aid for routine examination and the Specuvag AS as an aid for routine examination and procedures where smoke must be evacuated from the vaginal canal.

(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 K991827