SECTION 11

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared;

a. Applicant

Cervilenz, Inc.
17752 Sky Park Circle, Suite 285
Irvine, CA 92614
(949) 975-1515

b. Contact Person:

Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.
(949) 854-6314

c. Date Summary Prepared: June 7, 2001

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: Measuring Sound

b. Classification Name: Uterine Sound

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:	Cook OB/GYN
Device:	Teflon Uterine Sound
510(k) :	K870550
Date Cleared:	1987

Company:	Searle Laboratories
Device:	Mark-7 Disposable Uterine Sound
510(k) :	K760170
Date Cleared:	1976

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The Cervilenz Measuring Sound is a single use, disposable device used for measuring the depth and/or length of the uterus, cervix and vagina. The operating principle of the Cervilenz Measuring Sound is the same as that of cleared, commercially-available uterine sounds, and is based on insertion of the device into the cervical canal in order to obtain measurements. The Cervilenz Measuring Sound is fabricated from medical grade plastics of known biocompatibility and with a history of human use.

5. Statement of intended use:

The Cervilenz Measuring Sound is used for measuring the depth and/or length of the uterus, cervix and vagina.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

The technological characteristics of the Cervilenz Measuring Sound are comparable to those of the predicate and legally marketed uterine sounds, with regard to dimensions, materials of fabrication, and operating principle.

7. Brief summary of nonclinical tests and results:

The Cervilenz Measuring Sound was found to perform equivalently to commercially-available uterine sounds when evaluated for accuracy and reproducibility of measurements. Thus, the technological changes in the Cervilenz Uterine Sound do not raise any new issues of safety, effectiveness or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

Cervilenz, Inc.
c/o Judy F. Gordon, D.V.M.
Regulatory Consultant
ClinReg Consulting Services, Inc.
18732 Saginaw
IRVINE CA 92612

Re: K011840
Cervilenz™ Measuring Sound
Dated: June 11, 2001
Received: June 12, 2001
Regulatory Class: I
21 CFR§884.4530/Procode: 85 HHM

Dear Dr. Gordon:

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) 594-4639. 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 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,

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 (s)

510(k) Number (if known): K011840

Device Name: Cervilenz Measuring Sound

Indications for Use:

The Cervilenz Measuring Sound is used for measuring the depth and/or length of the uterus, cervix and vagina.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use ✓ OR Over-The-Counter Use ____
(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011840