ATTACHMENT C

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Name, Address, Telephone Number

Conceptus, Inc.
1021 Howard Ave.
San Carlos, CA 94070
(415) 802-7240

Contact Person

Cindy Domecus
Senior Vice President
Clinical Research, Regulatory Affairs, and Quality Assurance

Date of Summary

September 3, 1997

Device Names

Trade Name:	ERA Sheath
Common Name:	Resectoscope Sheath with Return Electrode
Classification Name:	Hysteroscope and Accessories

Device to Which Substantial Equivalence was Claimed

Substantial Equivalence was claimed to the Gynecare VersaPoint System, the FemRx PEARL Loop/OPERA System, the Karl Storz Continuous Flow Resectoscope, and the Conceptus FU*TURA* Sheath for Urological indications.

Device Description

The ERA Sheath is a tubular sheath device incorporating an electrosurgical return electrode. The Sheath is designed to fit over the shaft of a standard gynecological resectoscope to act as an electrical return, thereby, obviating the need for an electrosurgical dispersive pad. The design of the Sheath enables a uterine tissue resection or ablation procedure to be performed in isotonic solution instead of hypotonic solutions which are currently used in these procedures, thereby eliminating the risk of hyponatremia.

The ERA Sheath is composed of four structural elements: 1) a non-conductive sheath material which is placed over a standard continuous flow resectoscope, 2) a return electrode located on the distal end of the sheath with a conductor that runs along the sheath's surface to the proximal end of the sheath, 3) a standard wire connector lead which is used to attach the sheath to the return/patient outlet on the electrosurgical generator, and 4) an insulating outer jacket which is configured to expose the distal electrodes.

Intended Use

The ERA Sheath is indicated for use during the resection or ablation of unwanted or diseased uterine tissue.

Data Supporting Substantial Equivalence

Results from clinical evaluations, electrical safety testing, and histopathological evaluation of extirpated uterine tissue resected/ablated with the sheath were supplied in support of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 1997

Ms. Cindy Domecus
Senior Vice President
Clinical Research, Regulatory Affairs, and Quality Assurance
Conceptus, Inc.
1021 Howard Avenue
San Carlos, California 94070

Re: K972210
ERA Resectoscope Sheath
Dated: June 9, 1997
Received: June 11, 1997
Regulatory class: II
21 CFR §884.1690/Product code: 85 HIH

Dear Ms. Domecus:

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 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 requirement, 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/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
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): K972210

Device Name: ERA Sheath

Indications For Use:

The ERA Sheath is indicated for use during resection and/or ablation of unwanted or diseased uterine tissue.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter R. Salthy

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972210

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)