SEP 22 1998

K982565

Carl Schuh
10915 Lurline Avenue
Chatsworth CA 91311
510(k) submittal REF K982565
IUPC

Addendum C:

510(k) Summary of Safety and Effectiveness

submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92

The assigned 510(k) number is: K__982565___

Applicant information:

Date Prepared:	July 17, 1998
Name:	Carl Schuh
Address:	10915 Lurline Avenue Chatsworth, CA 91311
Contact Person:	Carl Schuh
Phone #:	818-882-6443 Fax 818-882-5054

Device Information:

Trade Name:	Easy Trans Tip
Common Name:	Intrauterine Pressure Transducer Catheter (IUPC)
Classification Name:	Intrauterine pressure Transducer

Equivalent Device(s): 3

Scientific Device Manufacturer, "Tip Trans"	510(k) # K 961290
Utah Medical, "IntransPlus IUP-400"	510(k) #K 905563/A and K 955443
Graphic Control, "Softrans 4000 IUPC"	510(k) #K 964279

Classification:
It has been determined that devices of this generic type have been previously classified as CLASS II Devices.

Product Description:
This 510(k) Notification is being submitted prior to the marketing introduction. This disposable device is a catheter with a pressure transducer located at the distal tip to monitor the intrauterine pressure. The sensor/transducer is a thick film/ceramic strain gage connected via 4 leads to a connector in proximal end. This end connector interfaces with a reusable cable designed for the proper connection to the monitor in use. The IUPC has a separate fluid infusion and

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sampling lumen with three holes near the distal end that terminates at the proximal end with a luer fitting/cap.

Incorporated in the connector housing at the proximal end is a switch for electronic zeroing of the transducer. This switch can also be used for periodic rezeroing of the system during use without the need for removal and replacement of the catheter.

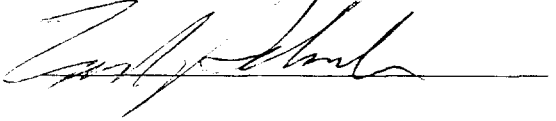
The distal end of the catheter holding the sensor is rounded and blunt while the catheter is soft, flexible polyurethane. This design minimizes the possibility of perforating the uterus while at the same time providing maximum comfort to the patient.

The introducer, is designed to ease the insertion of the flexible catheter and is of a split sheath design for easy removal from the catheter after insertion. A Velcro attachment devise is supplied to attach the catheter firmly in place on the patients thigh to prevent inadvertent slippage or dislodgment during use.

Intended Use:
The intrauterine pressure catheter is for use on patients requiring intrapartum intrauterine monitoring, amniofusion and amniotic fluid sampling.

Comparison to Predicate Device:
This catheter is substantially equivalent to numerous currently marketed IUP devices with regard to:

a) intended use, b) materials, c) dimensions, d) mechanical properties. Predicated devices include those made by Scientific Device Manufacturer (SDM), Utah Medical, Hewlett Packard, Graphic Control. No significant changes or modifications are being made from those predicate devices. Therefore, this device is substantially equivalent in safety and effectiveness to these devices and should be allowed to market this device.

Signed:  Carl Schuh

Position: Owner

Date: July 17, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 1998

Mr. Carl Shuh
10915 Lurline Avenue
Chatsworth, CA 91311-1638

Re: K982565
Easy Trans Tip (IUPC)
Dated: August 31, 1998
Received: September 4, 1998
Regulatory Class: II
21 CFR 884.2700/Procode: 85 KXO

Dear Mr. Shuh:

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 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,

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): K982565

Device Name: Easy Trans Tip

Indications For Use:

This intrauterine pressure monitoring catheter (IUPC) is for use on patients requiring intrapartum intrauterine pressure monitoring. Additionally it may be used for amniofusion and of Amniotic fluid sampling

(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 K982565