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JUL 14 1998

K974730
1 of 2

510(k) Summary

Graphic Controls

Manufacturer	Graphic Controls Corporation 189 Van Rensselaer Street P.O. Box 1271 Buffalo, NY 14240 Registration Number 1317188
Manufacturing Location	Graphic Controls Corporation 1 Carnegie Plaza Cherry Hill, NJ 08003 Registration Number 2243963
Contract Sterilizer	Isomedix 9 Apollo Drive Whippany, NJ 07981 Registration Number 2245604
Telephone	(716) 853-7500
Contact Person	Kathleen H. Selover Regulatory Affairs Specialist PHONE (716) 853-7500, ext. 7630 FAX (716) 847-7531 E-Mail: kathleen.selover@graphic-controls.com
Device Trade Name	Softrans® Plus Intrauterine Pressure Catheter System (IUP 5000 Softrans® Plus IUPC)
Common Name	Intrauterine Pressure Catheter with continuous temperature display
Classification Name	Catheter, Intrauterine and Introducer
Regulatory Reference	85 KXO
Predicate Device	Softrans® Intrauterine Pressure Catheter System WelchAllyn(DIATEK) SureTemp Thermometer System.

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Description

An intrauterine catheter with a pressure transducer at the tip, a thermistor located near the tip, a port for amnioinfusion and amniotic fluid sampling, signal wires, and an introducer which is removed after placement. System includes a reusable cable that contains a rezero mechanism, cable check and temperature display unit. An attachment strap is provided.

Catheters are packaged within a PETG tray with a heat sealed tyvek lid. Unit of sale is a case of 10 IUPC's.

Cables are packaged in protective wrap and corrugated shippers.

Intended Use

The Softrans® Plus System is used to obtain direct internal measurements of the intensity, duration, and frequency of uterine contractions during labor and to provide continuous monitoring and display of patient intrauterine temperature.

The catheter rests in the amniotic fluid between the fetus and uterine wall. During uterine contractions, the amniotic fluid is compressed; this pressure is transferred through the fluid and measured by the pressure transducer located at the tip of the catheter. The pressure signal is sent to the fetal monitor via the cable. The catheter also may be used for amnioinfusion of fluid into the uterus to enhance amniotic fluid volume, or for amniotic fluid sampling.

Intrauterine temperature is sensed by a thermistor located in the catheter. The return signal from the thermistor is sent to the temperature display unit located on the cable.

Physical and Technical Comparison

The intended use and application of Softrans® Plus IUPC System described in this submission is substantially equivalent to Softrans® IUPC System currently manufactured and marketed by Graphic Controls. Both systems measure uterine pressure by means of a pressure transducer located at the tip of an intrauterine catheter. The patient contacting surfaces and materials of the predicate and Softrans® Plus are identical.

In addition, Softrans® Plus has a temperature sensing mechanism near the catheter tip and a temperature display unit on the cable. The temperature sensing and display features of Softrans® Plus are substantially equivalent in technology and functionality to Welch Allyn (DIATEK) SureTemp Thermometer.

Performance Summary

FDA has not established special controls or performance standards for this device. Graphic Controls has established its own specifications and the product meets or exceeds those specifications.

Biocompatibility Testing

This device was subjected to biocompatibility testing and the data was submitted with the predicate device notification. The device was found to be non-irritating, non-cytotoxin and non-sensitizing.

Sterility and Shelf Life

Softran® Plus catheter will be sold as a sterile unit. The reusable cable is supplied non sterile. The expiration date is visible on the labeling for each catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1998

Ms. Kathleen H. Selover
Regulatory Affairs Specialist
Graphic Controls Corporation
189 Van Renssalaer Street
P.O. Box 1274
Buffalo, NY 14240-1274

Re: K974730
Softrans® Temp IUPC System
Dated: April 15, 1998
Received: April 16, 1998
Regulatory Class: II
21 CFR 884.2700/Procode: 85 KXO

Dear Ms. Selover:

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: K974730

Device Name: **Softrans** Temp IUPC System

Indications for Use:

The Softrans® Temp IUPC System may be used during the intrapartum period to monitor intrauterine pressure, to monitor intrauterine temperature, to amnioinfuse or to perform amniotic fluid sampling.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Presecription Use X OR Over-the-CounterUse _____
(Per 21CFR 801.109)

Donald J. Hilton for LLY
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974730