JUL - 8 1999

Ludlow Technical Products

Two Ludlow Park Drive
P.O. Box 297
Chicopee, MA 01021-0297
413-593-6400

K991235

510(k) Summary

Manufacturer	Ludlow Technical Products Two Ludlow Park Drive Chicopee, MA 01022 Registration Number 9001764
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	(413) 593-6400
Contact Person	Kathleen M. Murphy Regulatory Affairs Manager Phone: (413)-593-6400 Fax: (413) 593-6114
Device Trade Name	Softans Temp™ Intrauterine Pressure Catheter System (IUPC 5000 Softrans Temp™ IUPC)
Common Name	Intrauterine Pressure Catheter with continuous temperature display
Classification Name	Catheter, Intrauterine Pressure Catheter System
Regulatory Reference	85 KXO
Predicate Device	Softrans Temp™ Intrauterine Pressure Catheter System

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 Temp™ 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 amniotic fluid sampling. Intrauterine temperature is sensed by the thermistor located in the catheter. The return signal from the thermistor is sent to the temperature display unit located on the cable. Intrauterine temperature measurements correspond to oral temperature measurements and can be used in place of oral temperature measurements in laboring patients.
Physical and Technical Comparison	The intended use and application of the subject Softrans Temp™ described in this submission is substantially equivalent to the predicate Softrans Temp™ currently manufactured and marketed by Graphic Controls Corp (a division of Ludlow Technical Products). In addition, the intended use of the subject Softrans Temp™ now includes the addition of a claim in labeling stating that the intrauterine temperature measured by the device is clinically equivalent to oral temperature and that intrauterine temperature can be used in place of oral temperature measurements in laboring patients.
Performance Summary	FDA has not established special controls or performance standards for this device. Ludlow Technical Products 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	Softrans Temp™ 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

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Ms. Kathleen M. Murphy
Regulatory Affairs Manager
Ludlow Technical Products
Two Ludlow Park Drive
P.O. Box 297
Chicopee, MA 01021-0297

Re: K991235
Softrans Temp™ Intrauterine Pressure Catheter
System (IUP 5000, Softrans Temp™ IUPC)
Dated: April 6, 1999
Received: April 12, 1999
Regulatory Class: II
21 CFR §884.2700/Procode: 85 KXO

Dear Ms. Murphy:

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): K991235

Device Name: Softtrans Temp™ IUPC System

Indications for Use:

The Softrans Temp™ IUPC System may be used during the interpartum 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991235

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