

Graphic Controls Corporation

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P172 K964279



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
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Device Trade Name

Softtrans™ Intrauterine Pressure Catheter
System (IUP 4000 Softtrans™ IUPC)

Common Name

Intrauterine Pressure Catheter

Classification Name

Catheter, Intrauterine and Introducer

Regulatory Reference

85 KXO

Predicate Device

Softtrans™ Intrauterine Pressure Catheter
System

K964279
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Description	<p>An intrauterine catheter with a pressure transducer at 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 with a zero mechanism and an attachment strap.</p> <p>Catheters are packaged within a PETG tray with a heat sealed tyvek lid. Unit of sale is a case of 10 IUPC's.</p>
Intended Use	<p>Intended for use in measuring the intensity, duration, and frequency of uterine contractions during labor. Also, the catheter may be used for amnioinfusion of fluid into the uterus or to sample amniotic fluid.</p>
Physical/Technical Comparison	<p>Softtrans™ is equivalent to the predicate device. Physical and technical characteristics, including materials used in construction, size and intended use of the predicate device are comparable.</p>
Performance Summary	<p>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.</p>
Biocompatibility Testing	<p>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-cytotoxic and non-sensitizing.</p>
Sterility and Shelf Life	<p>Softtrans™ will be sold as a sterile unit except for the reusable cable. The expiration date is visible on the labeling for each catheter.</p>