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510(k) Summary

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Trade Name: STORC Intrauterine Pressure Catheter
Common Name: Intrauterine Pressure Catheter
Classification Name: Catheter, Intrauterine and Introducer

The legally marketed devices to which equivalence is claimed include the MX 4042 Series Intrauterine Pressure Catheter from Medex, the Meditrace Disposable Intrauterine Catheter from Graphic Controls, the Intrauterine Catheter from Telos, and the IUC - Intrauterine Catheter (INTRAN) from Utah Medical Products.

Description of the device: STORC™ is a Disposable Intrauterine Pressure Monitoring System. This product is a sterile, single patient use catheter.

Intended use: This catheter is for use on patients requiring intrapartum, intrauterine pressure monitoring.

The STORC Intrauterine Pressure Catheter is substantially equivalent to the predicate devices because:

It has the same intended uses, namely,

- intrauterine pressure measurement and monitoring
- port for amniotic fluid access,

It has the same basic technological characteristics as predicate devices, namely,

- pressure sensor located at catheter tip,
- soft tip for lower risk of perforation,
- markings for catheter insertion,
- low-cost disposable in order to avoid cross contamination,
- port and lumen with female luer connector for access to amniotic space,
- external zeroing of pressure.

It uses the same or similar materials, all of which have been shown to be biocompatible and to function well in the intended application,

The soft elastomeric tip is a further advantage that adds safety.

The safety and effectiveness are similar or better than existing devices as demonstrated in the laboratory and clinical testing.

Safety

Laboratory testing has shown that in the following areas the STORC Intrauterine Pressure Catheter is safe:

- Perforation: bench testing on fresh placenta showed that the STORC is less likely to perforate than predicate devices.
- Mechanical integrity: laboratory testing and basic design assure that no parts will come loose and be left in the patient.
- Biocompatibility and infection: independent lab testing show that the materials used in the STORC are safe for use in this application.

In addition, clinical studies including physician evaluation verified the safe nature of the STORC Intrauterine Pressure Catheter.

Effectiveness

The clinical trials showed that the STORC Intrauterine Pressure Catheter was as effective or more effective than the predicate devices in the following areas:

- integrity of intrauterine pressure signal
- ease of use
- amniotic space access
- device retention
- zeroing and drift signal stability

The laboratory testing verified the performance standards in terms of sensor accuracy, mechanical integrity, and overall performance.

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Date