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OCG Systems, Inc.
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Highland Park, Illinois 60035
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# 510(k) SUMMARY

## Disco™ Uterine Contraction Transducer and Accessories

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**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

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Contact Person: Fredric I. Orkin, President

Date Prepared: October 17, 1995

**Name of Device and Name/Address of Sponsor**

**Disco™ Uterine Contraction Transducer and Accessories**
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**Common or Usual Name:** Disco™

**Classification Name:** External uterine contraction transducer and accessories - 21 CFR 884.2720. The product code for such devices is 85HFM.

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**Predicate Devices:**

| | | |
|---|---|---|
| Corometrics | Fetal Monitor Model 116 and Accessories | **K831852** |
| Hewlett Packard | Physiological Pressure Transducer 1290C (Used with HP fetal Monitor HP8040) | **K840121** |

**Intended Use**

The Disco™ Uterine Contraction Transducer System is designed and intended for use in monitoring the progress of labor by measuring the duration, frequency and relative pressure of uterine contractions with a transducer strapped to the maternal abdomen.

**Technological Characteristics and Substantial Equivalence**

The Disco™ Uterine Contraction Transducer System is a non-sterile, single patient use external uterine contraction transducer and accessories. The system consists of a disposable belt with the transducer, an adapter cable with sensitivity switch for use with either Corometrics or Hewlett Packard patient monitor, and the package with appropriate label copy.

The Disco™ Uterine Contraction Transducer System uses a transducer that is placed in contact with the maternal abdomen and the output signal is displayed on a monitor and/or recording device. The transducer is composed of a mylar sheet with a pressure sensitive ink silk screened to its surface. This ink responds to changes in pressure from the foam pad by changing its electrical resistance. A series of conductive silver traces silk screened to a rigid ceramic substrate allow termination and measurement of this changing electrical resistance. A firm, yet flexible rounded elastomeric button is used to transfer the uterine contraction from the patient to the transducer. It is mounted in the center of the transducer and has an adhesive bond to the foam pad at its base. A thin, flexible, stranded, insulated wire is used to connect the transducer to the adapter cable. A two wire RJ-11 male telephone type connector is used as the electrical interface for the transducer. Because the pressure sensitive ink produces a stronger output signal than strain gauge type transducers, the Disco™ Uterine Contraction Transducer System has an output control switch to adjust the level of the output signal.

The Disco™ Uterine Contraction Transducer System covered by this submission is substantially equivalent to other legally marketed uterine contraction transducers.

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Specifically, this Disco™ Uterine Contraction Transducer is substantially equivalent to the Corometrics and the HP uterine contraction transducers. The Disco™ Uterine Contraction Transducer System has the same general intended use, similar principals of operation, and similar technological characteristics as the previously cleared referenced predicate device. Although there are minor differences in the characteristics of the Disco™ Uterine Contraction Transducer System and the referenced predicate device, those differences do not raise new questions of safety or efficacy.

The Disco™ Uterine Contraction Transducer System uses pressure sensitive ink technology rather than strain gauge transducer technology used by the predicate devices. In contrast to the strain gauge type transducer, the pressure sensitive ink technology has no moving parts. Also the Disco™ Uterine Contraction Transducer is intended for a single patient use only, whereas predicate uterine contraction monitors use a significantly more expensive transducer system and are routinely used on multiple patients, posing a potential risk of cross-contamination if they are not cleaned properly. The minor differences between the Disco™ Uterine Contraction Transducer System and the referenced predicate devices, raise no new questions of safety and effectiveness and are simply provided for customer convenience and cost savings.

**Performance Data**

Testing performed on the proposed product included clinical testing, bench testing, and electrical safety testing. In the clinical tests conducted the Disco™ transducer was compared to an internal catheter, to an external HP transducer, and to an external Corometrics transducer. In the bench tests conducted, the Disco™ Transducer was tested against a standard gauge, and against and external Corometrics transducer. A linearity and a hysteresis test was also performed. Finally, an independent laboratory tested the Disco™ transducer for EMI and leakage current. In all instances the proposed device met or exceeded all functional requirements and had virtually identical performance to marketed products.