scientific device manufacturer, inc.

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OCT 15 1996

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K961290

Applicant Information:

Date Prepared:	April 1, 1996
Name:	Scientific Device Manufacturer, LLC.
Address:	999 Andersen Drive, Suite 120 San Rafael, California 94901
Contact Person:	Richard C. Ball
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Device Information:

Trade Name:	SDM IUP-TipTrans and IUP-ProxiTrans
Common Name:	Intrauterine Pressure Transducer Catheter
Classification Name:	Intrauterine pressure Transducer

Equivalent Device:
IntranPlus (Utah Medical)
Fetal Monitoring Intrauterine Pressure Kit, #14099C (Hewlett Packard)

Classification:
In preparation of this PreMarket Notification, it was determined that devices of this generic type have been previously classified as Class II devices.

Product Description:
This 510(k) Notification is being submitted prior to marketing introduction of Scientific Device Manufacturer's Intrauterine Tip Transducer Catheter and its insertion device. Two models will be offered, one with a pressure transducer located at the proximal end using a fluid column to transmit pressure waves, the ther has the pressure transducer located in the distal tip. In both cases the transducer is a thick film/ceramic strain gage connected to a proximal connector. The connector interfaces with a reusable cable which is designed for proper connection to the monitor being used. Both devices will also have a separate fluid infusion and sampling lumen terminating in the side of the catheter near the distal end and integral to the connector at the proximal end.

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Incorporated in the tip transducer catheter is a signal interruption switch for electronic zeroing of the system following insertion and prior to commencement of use. This switch is also used for periodic rezeroing of the system during use without the need for removal and replacement of the catheter.

Both catheter tips have rounded, blunt ends while the catheter material is soft, flexible polyurethane. This design minimizes the possibility of uterine perforation while at the same time providing maximum comfort for the patient.

The catheter introducer, made of a somewhat stiffer polypropylene, is designed for easy insertion of the flexible catheter. It is of a split sheath design for simple removal following insertion. Also, a hook and loop attachment device is supplied for fixing the connector end of the catheter to the thigh following placement in order to prevent inadvertent dislodgement during use.

Intended Use:

The intrauterine pressure monitoring catheter (IUP) is for use on patients requiring intrapartum intrauterine monitoring, amniofusion, and sampling of amniotic fluid.

Comparison To Predicate Device:

Scientific Device Manufacturer's Intravascular Pressure Transducer Catheters are substantially equivalent to currently marketed IUP devices with regard to intended use, materials, dimensions and mechanical properties. Predicate devices include those made by Utah Medical, Corometrics, and Hewlett Packard. No significant changes or modifications were made from those predicate devices. SDM, LLC, therefore posits that its devices are equivalent in safety and effectiveness to those devices.

Signed: Richard C. Ball

Name: Richard C. Ball

Position: VP Regulatory Affairs and Quality Assurance

Date: April 1, 1996