

K961424

JUL 10 1996

UTAH MEDICAL
PRODUCTS INC.



SMDA 510(k) Summary

Trade Name: Intran Plus (Intran-500)
Common Name: Intrauterine Pressure Monitoring Catheter
Classification: Intrauterine Pressure Monitor and Accessories, 21 CFR §884.2700.

The UMP Intran 500 is the same device as Intran 400, Intran Plus, a sensor-tipped intrauterine pressure catheter used by obstetricians in monitoring the frequency and duration of contractions during labor and delivery, primarily indicated in "high risk" births. Intran-500 adds a molded clear plastic cylinder component which is attached to the catheter's amnio port, along with a plastic clip containing a color reference scale that fits over the plastic cylinder. The cylinder acts as a section in the liquid line that can be used by physicians for visualization of the color of a fluid sample drawn from the amniotic sac.

The safety of Intran Plus can be inferred directly from the fact that there have been no product liability lawsuits resulting from its use in an inherently risky procedure conducted by the most sued class of physicians in the U.S. in over 1.4 million uses since product introduction in 1991.

Both the Intran-500 and predicate Intran-400 devices are functionally identical and both have Amnio Ports that allow direct communication into the amniotic sac. The only difference between the two devices is the addition of a View Port and Color Tab Clip on the Intran 500, and the resulting package labeling and instructions for use.

Materials used in the Intran 500 that contact the patient are identical to materials used in the Intran-Plus. Biocompatibility and sterilization information is available from UMP upon request.


Kevin L. Cornwell
President & CEO