K960263

AUG 29 1996

510(k) Premarket Notification
Cervical Mucous Aspiration Catheter
Cook OB/GYN

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

Tammy Bacon
Cook OB/GYN
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-6500
January 17, 1996

Device

Trade Name:	Cervical Mucous Aspiration Catheter
Proposed Classification Name:	Aspirator, Endocervical

Predicate Devices:

The Cervical Mucous Aspiration Catheter is substantially equivalent to predicate devices in terms of indications for use and design. Predicate devices include the Aspirette Endocervical Aspirator manufactured by Unimar.

Device Description:

The Cervical Mucous Aspiration Catheter is used for cervical mucous aspiration for the evaluation of infertility. The Cervical Mucous Aspiration Catheter will be made from TFE and nylon. TFE is widely known and accepted in the medical field, therefore, biocompatibility is assured. Biocompatibility testing has been performed on the nylon and the results show a reasonable assurance of safety and effectiveness.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program. The device will undergo packaging and sterilization procedures similar to devices currently marketed and distributed by Cook OB/GYN. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.