K954903

APR 29 1996

510(k) Premarket Notification
Pedi Vaginal Aspirator
Cook OB/GYN

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

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Device

Trade Name:	Pedi Vaginal Aspirator
Proposed Classification Name:	Catheter, Pediatric, General & Plastic Surgery

Predicate Devices:

The Pedi Vaginal Aspirator is substantially equivalent to predicate devices in terms of indications for use. Predicate devices include the Bard® Rubber Utility Catheter, Radiopaque manufactured by Bard.

Device Description:

The Pedi Vaginal Aspirator is used to aspirate vaginal secretions to evaluate female pediatric patients with vaginitis and/or possible sexual abuse. This device will be made from polyurethane and polyethylene.

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 and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.