

510(k) Summary

K961506

Submitted By: Imagyn Medical, Inc.
27651 La Paz Road
Laguna Niguel, CA 92656-3917
(714) 362-2500
Contact: Debra A. Rinderer

Summary Preparation: February 29, 1996

Device: MicroSpan Hysteroscope Sheath

Predicate Devices: Imagyn Hysteroscope Sheaths
Olympus Hysteroscope 4/5 mm System
Circon ACMI Office Operative Hysteroscope Sheath
Karl Storz Mini-Hysteroscopy Operating Sheath

Device Description: The MicroSpan Hysteroscope Sheath is offered with irrigation/insufflation and aspiration ports and an instrument channel. The device is provided sterile, for single-use, and is made from both metal and plastic components.

Intended Use of Device: The MicroSpan Hysteroscope Sheath is indicated for use in providing access to the uterine cavity for the Imagyn Hysteroscope or other hysteroscopic instruments during diagnostic and operative hysteroscopic procedures.

Technological Comparisons: The device has equivalent technological characteristics to the predicate devices, as well as to numerous other legally marketed devices, to achieve hysteroscope and/or hysteroscopic instrument insertion without loss of uterine distention.

Performance Summary: Non-clinical tests were performed to demonstrate that the device performed according to its description and intended use. Leak and flow testing performed showed adequate performance for the intended use.

JUL - 3 1996