

MAY -5 1997

510(k) Summary K970750

Submitter: Imagyn Medical, Inc.
27651 La Paz Road
Laguna Niguel, CA 92677-3917
(714) 362-2500
Contact: Debra A. Rinderer

Summary Preparation: April 18, 1997

Device: MicroSpan Insemination System

Predicate Device(s): Imagyn Intrauterine Insemination Device
Cook OB/GYN Coaxial Catheter Set
Cook OB/GYN Shepard Intrauterine Insemination Catheter
Cook OB/GYN Jansen-Anderson Insemination Set
Cook OB/GYN Spirtos Coaxial Catheter Set

Device Description: The MicroSpan Insemination System is a sterile device consisting of two components: the MicroSpan Access Catheter (introducer) and the MicroSpan Delivery Catheter. The MicroSpan Insemination System is designed to be introduced through the MicroSpan Hysteroscope Sheath for intrauterine insemination procedures or introduced through the operative channel of a laparoscope for laparoscopic instillation and/or aspiration of media.

Intended Use of Device: Used for intrauterine insemination. The MicroSpan Delivery Catheter is designed to fit through the larger diameter MicroSpan Access Catheter for delivery of washed spermatozoa to the uterine cavity or for laparoscopic instillation and/or aspiration of media. Laparoscopically, the device is specifically intended for use to aspirate ascitic fluids, aspirate fluid from the cul-de-sac for cytologic screening and bacteriologic cultures, irrigation and aspiration of larger volumes of fluid from ovarian tumors, irrigation and rinsing of the operative field, aspiration of bloody fluid resulting from a tubal pregnancy or post operative bleeding, and instillation of sterile saline or Ringer's solution.

Technological Comparisons: The MicroSpan Insemination System has equivalent technological characteristics to the predicates to achieve intrauterine insemination or laparoscopic instillation and/or aspiration of media.

Performance Summary: Non-clinical tests were performed to demonstrate that the device performed according to its description and intended uses. All tests showed adequate performance of the device for its intended uses.