OCT 1 - 2004

510(k) SUMMARY

K041062

Submitted By:

Cindy Rumple
Cook OB/GYN
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891
April 15, 2004

Device

Trade Name:	Intrauterine Venogram Needle Set
Proposed Classification Name:	Cannula Manipulator/Injector, Uterine Blood, Lancet-Venous System

Intended Use:

The Intrauterine Venogram Needle Set is intended for hysterography and intrauterine venography for assessment of chronic pelvic pain/congestion

Predicate Devices:

The Intrauterine Venogram Needle Set is similar with respect to indications for use and technology to exist predicate devices in commercial distribution. Specifically, the Intrauterine Venogram Needle Set is similar to the Ott Intrauterine Catheter Set (K891290) manufactured by Cook OB/GYN, and the Echotip Disposable Percutaneous Needle (Exempt) manufactured by Cook OB/GYN.

Device Description:

The Intrauterine Venogram Needle Set contains two components: a catheter sheath and a needle. The single-lumen access catheter has a bulb tip, tubing, connector cap and lock assembly manufactured from nylon. The injection needle is manufactured from stainless steel with a polycarbonate hub. The Intrauterine Venogram Needle set is supplied sterile in lengths from 15 cm to 30 cm and is packaged in a sealed peel-open container.

Substantial Equivalence:

The Intrauterine Venogram Needle Set 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 - 2004

Ms. Cindy Rumple
Regulatory Affairs Technical Writer
Cook Ob/Gyn
1100 W. Morgan Street
SPENCER IN 47460

Re: K041062
Trade/Device Name: Intrauterine Venogram Needle Set
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 85 LKF
Dated: August 23, 2004
Received: August 24, 2004

Dear Ms. Rumple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K041062

Device Name: Intrauterine Venogram Needle Set

Indications for Use: The Intrauterine Venogram Needle Set is intended for hysterography and intrauterine venography for assessment of chronic pelvic pain/congestion.

Prescription Use___X___ (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

/Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041062