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510(k) SUMMARY

Submitted by:

Cindy Foote
Regulatory Affairs Specialist
Cook Urological, Incorporated
1100 West Morgan Street
Spencer, IN 47460
February 29, 2008

Device:

Trade Name: INJEKT™ Filiform Injection Needle

Proposed Classification Name: Endoscopic Injection Needle, Gastroenterology-Urology
21 CFR Part 876.1500
Class II, FBK

Predicate Devices:

The INJEKT™ Filiform Injection Needle is similar with respect to indications for use and technology to existing predicate devices. Specifically, the INJEKT™ Filiform Injection Needle is similar to the Cook® Injection Needle (K022484), manufactured by Cook Urological, Incorporated, the Uroplasty Rigid Endoscopic Needle (K051905) manufactured by Uroplasty, Incorporated, the Advanced Uroscience Injection Needle (K982890), manufactured by Advanced Uroscience, Incorporated, and the Vance Cystoscopic Injection Needle (812057), manufactured by Cook® Urological, Incorporated. Please refer to **Attachment C** for marketing and FDA information regarding the predicate devices.

Device Description:

The INJEKT™ Filiform Injection Needle is used to inject legally marketed therapeutic agents into the genitourinary system, most specifically for vesicoureteral reflux (VUR) in the pediatric population and for bladder neck injection for the population as a whole. The INJEKT™ Filiform Injection Needle consists of a needle and an outer sheath with a filiform tip. Hash marks on the outside of the needle are used to assess proper depth of placement. The filiform tip of the needle acts as a landmark for easier access to precise injection location. The needle exits the side of the device to allow precise injection location and assures additional safety for the patient against inadvertent stick when the needle is retracted. The devices are provided sterile and are intended for one time use.

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Substantial Equivalence:

The Cook® Cervical Ripening Balloon is comparable with respect to intended use to the published predicate device description and meets the requirements for 510(k) substantial equivalence.

Test Data:

Biocompatibility, sterility and performance testing were performed in accordance to Food and Drug Administration guidance's and recognized international standards. Testing data and information is included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2008

Ms. Cindy Footc
Regulatory Affairs Specialist
Cook Urological, Incorporated
1100 W. Morgan Street
SPENCER IN 47460

Re: K082319
Trade/Device Name: INJEKT™ Filiform Injection Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: August 11, 2008
Received: August 13, 2008

Dear Ms. Foote:

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 (PMA), 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K082319

Indications for Use

510(k) Number (if known): K082319

Device Name: INJEKT™ Filiform Injection Needle

Indications for Use: Used to inject legally marketed therapeutic agents into the genitourinary system, most specifically for vesicoureteral reflux (VUR) in the pediatric population and for bladder neck injection for the population as a whole.

Prescription Use? ___X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082319