K113634

Attachment E - 510(k) Summary

FEB 14 2012

Name:	Cook Ireland Ltd
Address:	O'Halloran Road National Technology Park Limerick, Ireland
Phone:	+353 61 334440
Fax:	+353 61239293
Contact Persons:	Laura Guinane, Regulatory Affairs Specialist Emmett Devereux, Director of Quality & Regulatory Affairs
Phone:	+353 61 334440
Fax:	+353 61 239293
Date:	December 7, 2011
Trade Name:	Injekt™ Cysto Flexible Injection Needle
Common Name:	Flexible Injection Needle
Classification Name:	Endoscopic Injection Needle, Gastroenterology-Urology (21 CFR 876.1500, Product Code: FBK)
Legally Marketed Devices:	Cook Injection Needles
Description of the Device:	This device is a flexible, sheath covered injection needle The device consists of a device handle, flexible outer sheath, and needle assembly. The device has an outer diameter of 6Fr, a working length of 70 cm and a 23 ga needle for injection of legally marketed therapeutic agents into the lower urinary tract through the working channel of a cystoscope.
Indications for use:	This device is used to inject legally

	marketed injectable therapeutic agents into the lower urinary tract through the working channel of a cystoscope.
Comparison of Characteristics:	The modified device is substantially equivalent to the currently marketed device, the Cook Injection Needles, as cleared by K022484.
Performance Data:	The risks associated with the modifications to our subject device have been adequately addressed through our Design Control Process. Performance standards under Section 514 of the Federal ~Food, Drug and Cosmetic Act applicable to Injekt™ Cysto Flexible Injection Needle have not been established by the Food and Drug Administration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Laura Guinane
Regulatory Affairs Specialist
Cook Ireland Ltd.
O'Halloran Road, National Technology Park
LIMERICK
IRELAND

FEB 14 2012

Re: K113634
Trade/Device Name: Injekt™ Cysto Flexible Injection Needle
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: January 19, 2012
Received: January 23, 2012

Dear Ms. Guinane:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment A - Indications for Use

Device Name: Injekt™ Cysto Flexible Injection Needle

Indications for Use:

This device is used to inject legally marketed injectable therapeutic agents into the lower urinary tract through the working channel of a cystoscope.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K 113634