K022484

OCT 25 2002

510(k) Premarket Notification
Cook Injection Needles
Cook Urological, Inc.

I. 510(k) SUMMARY

Submitted By:

Debbie Schmitt
Cook Urological
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891

Date: July 26, 2002

Device

Trade Name:	Cook Injection Needles
Proposed Classification Name:	Class II Needle, Endoscopic 78 FBK
Predicate Devices:	Specifically, the Cook Injection Needles are similar to The Advanced UroScience Injection Needles (K#982890), The Martech Endoscopic Needle (K#960519), The Genyx Medical Injection Needles (K#990996), The Tunis Transurethral Injection/Aspiration System Probe Devices (K#983765) and The Vance Cystoscopic Injection Needle (K#812057).
Device Description:	The Cook Injection Needle will consist of a Polyurethane Catheter with a Stainless Steel Needle Tip and a luer lock hub. The Catheter sizes range from 3.7 French to 9 French and will be 15cm to 65cm's in length. The Stainless Steel Needle portion will be 16 Gage though 25 Gage.
Substantial Equivalence:	These Devices will be manufactured according to specified controls and a Quality Assurance Program. The devices will undergo packaging similar to the devices currently marketed and distributed by Cook Urological. Being similar with respect to indications for use, materials and physical construction to predicate devices, these devices meet 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 2 5 2002

Ms. Debbie Schmitt
Regulatory Affairs Manager
Cook® Urological
1100 W. Morgan Street
SPENCER IN 46460

Re: K022484
Trade/Device Name: Cook Injection Needles
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FBK
Dated: July 26, 2002
Received: July 29, 2002

Dear Ms. Schmitt:

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 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.

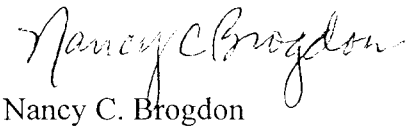
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022484

Device Name: Cook Injection Needles

Indications For Use: The Cook Injection Needles are used to deliver a variety of injectable materials into tissues during laparoscopic, hysteroscopic, cystoscopic, endoscopic transurethral procedures and open surgical procedures. The type of material to be injected will be dependent on the nature of the procedure. The needle is intended to be used with legally marketed drugs and devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter___.

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022484