

NOV - 3 1997

**510(k) Premarket Notification
Biopsy Needle
COOK INCORPORATED**

K9 73565

ATTACHMENT 5

SMDA SUMMARY

**510(k) Premarket Notification
Biopsy Needle
COOK INCORPORATED**

□ Safety and Effectiveness Information

Submitted By: April Lavender, RAC
Vice President, Regulatory Affairs
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235

Device:

Trade Name: Quick-Core™ Biopsy Needle
Proposed Classification Name: Gastroenterology-Urology Biopsy Instruments
21 CFR Part 876.1075 (74DQT)

Predicate Devices:

The Quick-Core™ Biopsy Needle has the same intended use, materials of construction, and technological characteristics as the ProAct Biopsy Needle for soft tissue biopsy procedures.

Device Description:

The Quick-Core™ Biopsy Needle is used for soft tissue biopsy procedures. The device will be constructed of stainless steel and polycarbonate in 14, 15, 16, 18, 19 and 20 gauge and 6, 9, 15, 20 and 48 cm lengths. It will be supplied sterile, intended for one-time use.

Substantial Equivalence:

This device will be manufactured according to specified process controls and a Quality Assurance Program. This device will undergo packaging similar to the devices currently marketed and distributed by COOK INCORPORATED. This device will undergo sterilization similar to the devices currently marketed and distributed.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 1997

Ms. April Lavender, RAC
Vice President
Regulatory Affairs
Cook Inc.
925 South Curry Pike, PO Box 489
Bloomington, Indiana 47402

Re: K973565
Trade Name: Quick-Core™ Biopsy Needle
Regulatory Class: II
Product Code: KNW
Dated: October 9, 1997
Received: October 14, 1997

Dear Ms. Lavender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

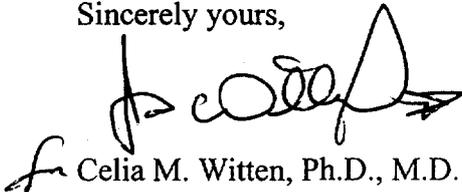
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for

devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Premarket Notification
Biopsy Needle
COOK INCORPORATED**

510(k) Number (if known): K973565

Device Name: Quick-Core™ Biopsy Needle

Indications for Use:

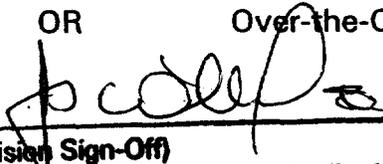
Used for soft tissue biopsy. Supplied sterile in peel-open packages. Intended for single procedure use.

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-the-Counter Use _____


(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K973565