

**510(k) Premarket Notification
MRI Needles
COOK INCORPORATED**

K963565

J. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 14 1997

Submitted By:

April Lavender, RAC

COOK INCORPORATED

925 South Curry Pike

P.O. Box 489

Bloomington, IN 47401

4 September 1996

Device:

Trade Name:

MRI Needles

Proposed Classification Name:

Class I exempt, §878.4800

Needles, Aspiration and Injection, All Types, 79GAA

Needles, Percutaneous Biopsy, All Types, 79MJG

Needles, Biopsy Cardiovascular, 79DWO

Indications for Use

MRI needles are intended for use with 1.5 Tesla (or lower field strength) magnetic resonance imaging procedures, including initial puncture, aspiration and injection, biopsies and diagnostic sampling.

Predicate Devices:

The MRI Needle is substantially equivalent to other devices intended for use in conjunction with magnetic resonance imaging in terms of indications for use, design, construction and materials' equivalence. Specifically, this device is similar to COOK INCORPORATED pre-Amendment and predicate disposable and reusable needles, magnetic resonance imaging needles manufactured by E-Z-EM[®], INC. in Westbury, New York, (K#882601), and devices marketed in Europe by William Cook Europe A/S, Denmark.

Device Description:

The MRI Needle is intended for use for the same indications as the predicate devices listed above. These indications include initial puncture, aspiration and injection, biopsies, diagnostic sampling and other interventional procedures. The materials used in this device are widely used in medical device manufacturing and their biocompatibility has been verified. In addition, design validation studies have been performed to assure the device can be expected to perform its intended function when used according to the recommendations in the product's labeling which will be provided with the device. The device will be made in 25 to 16 gage diameters, in lengths from 2.5 cm to 20 cm. It will be supplied sterile.

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. 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K963565
MRI Needles
Regulatory Class: II
Product Code: FCG
Dated: May 1, 1997
Received: May 2, 1997

JUL 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.

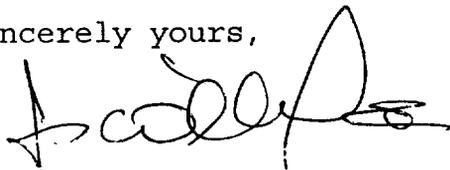
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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,



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
MRI Needles
COOK INCORPORATED

510(k) Number (if known): K963565

Device Name: MRI Needles

Indications for Use:

MRI needles are intended for use with 1.5 Tesla (or lower field strength) Magnetic Resonance Imaging procedures, including initial puncture, aspiration and injection, biopsies and diagnostic sampling.

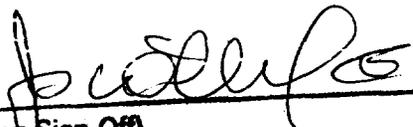
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K963565