

MAY 13 1999

IMS
International Medical Systems
PO Box 4936 Annapolis, Maryland 21403

K990515

510(k) Summary

Submitted by:
Charles Simonelli
28 Spring Lane
Farmington, CT 06032
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Date Submitted: February 2, 1999

Classification, Common or Usual Name, Device Name:

Trade Name: Mathis Vertebral and Bone Biopsy System

Common Name: Bone Marrow Biopsy Needle

Classification Name: Needle, Biopsy, Cardiovascular
General and Plastic Surgery-878
Classification Number-79DWO
Regulation Number-878.4800
Class I

Predicate Device:

Manan Bone Marrow Aspiration / Biopsy Needle (K890925). The device is available in the following sizes:

- 8 ga x 4"
- 8 ga x 6"
- 11 ga x 4"
- 11 ga x 6"
- 13 ga x 4"
- 13 ga x 2-1/2"

Device Description:

The Mathis Vertebral and Bone Biopsy System is a standard bone marrow biopsy needle consisting of a cannula with a sharpened distal end and a stylet received coaxially in the cannula and having a sharpened distal end protruding from the distal end of the cannula. The cannula is insert molded to a hub with standard threadable lug tabs. The stylet is insert molded to a standard hub. When the stylet assembly is placed into the cannula assembly, the entire cannula/stylet unit can be threaded into a removable gripable handle.

Indications For Use:

The Mathis Vertebral and Bone Biopsy Systems are intended for use by physicians performing bone marrow biopsy procedures.

Technological Characteristics:

The key technological characteristic involved in bone marrow biopsy procedures is the effect of the point geometry of the cannula and protruding stylet on the units ability to penetrate the outer layer of the bone in a controllable manner. Stylets and cannula presently in the market have been designed with various sharpened distal ends to facilitate bone penetration. The Mathis Vertebral and Bone Biopsy System will not substantially differ its stylet and cannula point geometry from product currently available in the market.

Non-Clinical Data:

Part specification and prints for the Mathis Vertebral and Bone Biopsy System show it to be substantially equivalent to the Manan Bone Marrow Aspiration/Biopsy Needle.

Clinical Performance Data:

None available at this time.

Conclusions:

It is the conclusion of International Medical Systems that the Mathis Vertebral and Bone Biopsy System is substantially equivalent, relative to its key technical performance characteristics, to product already available in the market.



MAY 13 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Charles Simonelli
Quality Assurance Manager
International Medical Systems
P.O. Box 4936
Annapolis, Maryland 21403

Re: K990515
Trade Name: Mathis Vertebral and Bone Biopsy System
Regulatory Class: II
Product Code: KNW
Dated: February 9, 1999
Received: February 18, 1999

Dear Mr. Simonelli:

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.

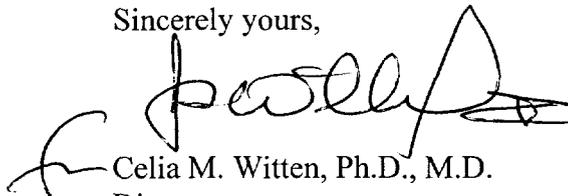
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. Charles Simonelli

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 "C. Witten", is written over the typed name.

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

International Medical Systems
PO Box 4936
Annapolis, Maryland 21403

Statement For Indications For Use:

510(k) Number (if known): K 990515

Device Name: Mathis Vertebral and Bone Biopsy System

Indications For Use:

The Mathis Vertebral and Bone Biopsy Systems are intended for use by physicians performing bone marrow biopsy procedures.

Prescription Use X
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 12990515