FEB 1 1 2005 K043523

TAB 4

PREMARKET NOTIFICATION [510(K)] SUMMARY

December, 2004

Trade Name:	InterV® brand SnareLok Bone Marrow Biopsy Needle
Common Name:	Biopsy needle
Classification Name:	Instrument, biopsy (per 21 CFR section 876.1075)
Manufacturer's Name:	Medical Device Technologies, Inc. 3600 SW 47th Avenue Gainesville, FL 32608
Corresponding Official:	Nicohl Wilding Manager Regulatory Affairs 241 W. Palatine Road Wheeling, IL 60090 Phone: (800) 424-6779 ext, 331 Fax: (847) 637-3334
Predicate Device(s):	Medsol Corporation Goldenberg Bone Marrow Biopsy Needle, K983187. Medical Device Technologies, Inc. Manan Bone and Bone Marrow Biopsy Needle, K980196
Device Description:	The biopsy instrument is a sterile disposable device which features a cannula assembly containing an outer cannula with an inner spiral snare tube at the distal tip. The device has a handle with a snare lever that can be rotated 180° to engage the snare when a biopsy sample needs to be taken. Finally the device has a stationary stylet to prevent coring during advancement, and a stylet cap which mates to the handle. Three sizes are available; 8, 11 and 13 gauge needles. The 8 and 11 gauge needles are sold in 4" and 6" lengths and have a tip configuration identical to the geometry of the existing Medical Device Technologies Manan Bone and Bone Marrow Biopsy Needle. The 13 gauge needles are sold in 2" and 3" lengths and have a less tapered tip configuration identical to a bone marrow needle currently manufactured by Ranfac.

The needle is used by advancing it with the stylet in place, to the site of bone or marrow sampling. The needle is advanced with gentle but firm pressure, with alternating clockwise-counterclockwise rotational motion. Once the needle is in position, the stylet and stylet cap are removed and the needle is advanced with additional rotation to obtain the marrow sample. Aspiration can be used to obtain the sample by positioning a syringe to the hub of the needle and applying suction. For biopsy, the needle is advanced to a new location with rotating motion until adequate marrow is obtained. The Snare lever is rotated clockwise to its closed position to capture the marrow sample. A probe is provided which has markings that can be used to estimate the length of the sample before the needle is removed from the patient. Once the needle is removed, the SnareLok lever is turned to the open position. The sample can then be expelled from the proximal end of the needle using the probe.

A Probe Guide is also included with the SnareLok Bone Marrow Needle to provide an easy method to align the probe in the needle tip for sample expulsion, and to protect users from the sharp tip during handling.

Intended Use: For harvesting bone and/or bone marrow specimens.

Technological Characteristics: The biopsy needles are available in 8-13 gauge sizes and lengths from 2 to 6 inches.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Ms. Nichol Wilding
Manager Regulatory Affairs
Medical Device Technologies, Inc.
241 W. Palatine Road
Wheeling, Illinois 60090

Re: K043523
Trade/Device Name: InterV® Brand SnareLok Bone Marrow Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW and FCG
Dated: December 7, 2004
Received: December 20, 2004

Dear Ms. Wilding:

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.

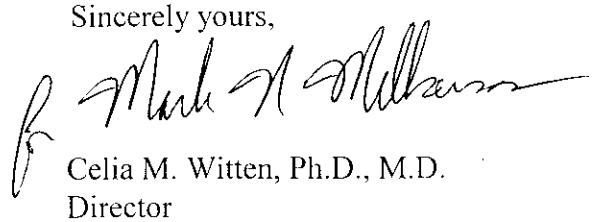
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Section 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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE

510(k) Number: K043523

Device Name: InterV® brand SnareLok Bone Marrow Biopsy Needle

Indications for Use:

The SnareLok Bone Marrow Biopsy Needle is intended for harvesting bone and/or bone marrow specimens.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR **Over-The-Counter Use** ____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043523