NOV - 1 2005

TAB 4

PREMARKET NOTIFICATION [510(K)] SUMMARY

Trade Name:	Manan Bio-Cut Soft Tissue Biopsy Needle
Common Name:	Biopsy needle
Classification Name:	Instrument, biopsy (per 21 CFR section 876.1075)
Manufacturer's Name:	Manan Medical Products, Inc. 241 W. Palatine Road Wheeling, IL 60090
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):	Manan Super-Core Biopsy Needle K950732. Medical Device Technologies Super-Core Biopsy Needle K974814
Device Description:	The biopsy instrument is a sterile disposable device which features a stainless steel cannula with an echogenic tip, and a stainless steel stylet which is spring loaded and fitted into a plastic handle permitting single handed specimen collection. Sizes are available in 14 - 20 gauge needles. The length of the needles ranges between 9 and 20 cm. The needle is used by advancing the entire device to the site of soft tissue sampling. The needle is advanced with gentle but firm pressure. Once the needle is in position, the sample is taken and the device is removed from the sampling site. The sample can then be expelled from the stylet notch.
Intended Use:	For harvesting soft tissue biopsy specimens.
Technological Characteristics:	The biopsy needles are available in 14 - 20 gauge sizes and lengths from 9 to 20 centimeters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2005

Nicohl Wilding
Manager Regulatory Affairs
Manan Medical Products, Inc.
241 West Palatine Road
Wheeling, Illinois 60090

Re: K052802
Trade/Device Name: Manan Bio-Cut Soft Tissue Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: October 26, 2005
Received: October 27, 2005

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.

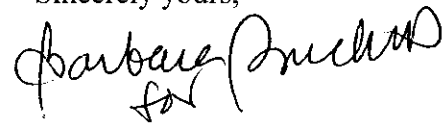
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052802

INDICATIONS FOR USE

510(k) Number: _____

Device Name: Manan Bio-Cut Soft Tissue Biopsy Needle

Indications for Use:

The Bio-Cut Soft Tissue Biopsy Needle is intended for harvesting soft tissue biopsy specimens.

☒ **Prescription Use** and/or ☐ **Over-The-Counter Use**
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

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

510(k) Number K052802