JUN 2 6 2002

K021137

Section II - Summary of Safety and Effectiveness

(1) Contact Information

Vincent Cutarelli
Vice President, Regulatory Affairs
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(2) Company Information

Sanarus Medical, Inc.
5880 W. Las Positas Blvd., Suite 52
Pleasanton, CA 94588
Telephone: (925) 460-6080
FAX: (925) 460-6084
949

(3) Device Name

Sanarus Core Tissue Biopsy System

(4) Device Description

The Sanarus Centrica™ Core Tissue Biopsy System consists of a sticking probe, tissue cutter, control unit and specimen container. The sticking probe is operated by the control unit and utilizes cold temperatures at its tip to engage the tissue to be sampled. The tissue cutter is coaxially mounted around the sticking probe and is used to core the tissue specimen. The tissue cutter will be available in several gauge sizes and lengths.

(5) Indications for Use

The device is indicated for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

The device is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

(6) Name of Predicate or Legally Marketed Device

Sanarus Core Tissue Biopsy System

(7) Substantial Equivalence

The Sanarus Centrica™ Core Tissue Biopsy System is substantially equivalent to the Sanarus Core Tissue Biopsy System that was determined to be substantially equivalent on May 3, 2001 (reference K013528).

The Sanarus Centrica™ Core Tissue Biopsy System has the same indications for use and technological characteristics as the predicate device. The patient contact components and component materials for obtaining core biopsy samples in both the new and predicate device are the same. The packaging materials, packaging configurations, sterilization methods and sterility assurance level are also equivalent.

Based on the indications for use, technological characteristics and testing results, the Sanarus Centrica™ Core Tissue Biopsy System does not raise significant new questions of safety and effectiveness.

(8) Performance Data Summary

Testing confirms that the quality of samples obtained with the Sanarus Centrica™ Core Tissue Biopsy System is equivalent to the predicate device and that the use of a cooled probe to engage the tissue does not affect the histological evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Vincent Cutarelli
Vice President, Regulatory Affairs
Sanarus Medical, Inc.
5880 W. Las Positas Boulevard, Suite 52
Pleasanton, California 94588

Re: K021137
Trade Name: Sanarus Centrica Core Tissue Biopsy System
Regulation Number: 876.1075
Regulation Name: Gastroenterology/Urology Biopsy Device
Regulatory Class: II
Product Code: KNW
Dated: April 5, 2002
Received: April 9, 2002

Dear Mr. Cutarelli:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for 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: K021137

Device Name: Sanarus Centrica™ Core Tissue Biopsy System

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

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

510(k) Number K021337

Prescription Use: X
(Per 21 CFR 801.109)