K020054

OCT 16 2002

Section II - Summary of Safety and Effectiveness

(1) Contact Information

Vincent Cutarelli
Vice President, Regulatory Affairs
Telephone: (949) 768-1184 ext. 105

(2) Company Information

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

(3) Device Name

Sanarus Indica Marker System

(4) Device Description

The Sanarus Indica Marker System consists of a delivery device (applier), introducer cannula and non-absorbable tissue marker that is clearly visible on standard radiographs and ultrasound.

(5) Indications for Use

The Sanarus Indica Marker System is indicated for use to attach to soft tissue, including breast tissue, following an open surgical or percutaneous biopsy procedure and to radiographically and radiologically mark the location of the biopsy procedure.

(6) Name of Predicate or Legally Marketed Device

Senorx, Inc. Gel Mark Biopsy Site Marker (reference K000060)
Advanced UroScience, Inc. Tissue Marker (reference K001807)
Inrad, Inc. UltraClip Tissue Marker (reference K993785)

K020054

(7) Technological Characteristics and Performance Summary

The design, construction and materials are similar to or equivalent to the marketed predicate devices. Biocompatibility and bench testing have demonstrated that the device is safe and effective and that its performance is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2002

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

Re: K020054
Trade/Device Name: Sanarus Indica Marker System
Regulation Number: 878.4750; 878.4300
Regulation Name: Implantable staple; Implantable clip
Regulatory Class: Class II
Product Code: GDW; FZP
Dated: July 17, 2002
Received: July 18, 2002

Dear Mr. Cutarelli:

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 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" (21 CFR 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,

Miriam C. Provost

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: K020054

Device Name:

Indications for Use: The Sanarus Indica Marker System is indicated for use to attach to soft tissue, including breast tissue, following an open surgical or percutaneous biopsy procedure and to radiographically and radiologically mark the location of the biopsy procedure.

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

Miriam C. Provost

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

510(k) Number K020054

Prescription Use: X
(Per 21 CFR 801.109)