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SENORX

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5. 510(K) SUMMARY

Date prepared	April 14, 2008
Name	SenoRx, Inc. 11 Columbia Aliso Viejo, CA 92656 T. 949.362.4800; F. 949.362.0300
Contact person	Eben Gordon Vice President, RA/QA SenoRx, Inc. T. 949.362.4800; F. 949.362.0300
Device name	StarchMark
Common name	Biopsy site marker
Classification name	Implantable Clip
Classification regulation	878.4300 NEU
Predicate devices	K031938; Gel Mark III Biopsy Site Marker; Clearance date: 9/5/2003
Description	The StarchMark Biopsy Site Marker is a sterile, disposable applicator containing 4 resorbable polysaccharide (starch) pellets and a polylactic/polyglycolic acid-based co-polymer (PLA/PGA) pellet with an embedded radiopaque wireform.
Indications for use	The StarchMark Biopsy Site Marker is intended to radiographically mark breast tissue during a percutaneous breast biopsy procedure.
Summary of substantial equivalence	Preclinical studies conducted included *in vitro* laboratory studies to demonstrate that the StarchMark Biopsy Site Marker performed as intended under simulated use conditions. Biocompatibility testing was performed to demonstrate that the starch pellet meet ISO 10993-1 requirements. In a porcine study designed to evaluate the control of bleeding, the StarchMark marker demonstrated superiority over the control group in the cessation of bleeding time. The StarchMark marker has the following similarities to the previously cleared predicate device: • Same indications for use; • Same intended use; • Same intended treatment site; • Same operating principle; • Same technological characteristics; • Same packaging; and

- Same sterilization method.

In summary, the StarchMark Biopsy Site Marker as described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2008

SenorRx, Inc.
% Mr. Eben Gordon
VP, Regulatory Affairs & Quality
Assurance
11 Columbia
Aliso Viejo, California 92656

Re: K081085
Trade/Device Name: StarchMark Biopsy Site Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: July 29, 2008
Received: July 30, 2008

Dear Mr. Gordon:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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 (if known): K081085

Device Name: StarchMark Biopsy Site Marker

Indications for Use:

The StarchMark Biopsy Site Marker is intended to radiographically mark breast tissue during a percutaneous breast biopsy procedure.

Prescription Use __X__ AND/OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milkereit

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

510(k) Number K081085