



Food and Drug Administration
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July 19, 2016

SenoRx Incorporated
Ms. Sarah McCartney
Senior Regulatory Affairs Specialist
1625 West 3rd Street
Tempe, Arizona 85281

Re: K161805

Trade/Device Name: EnCor MRI Introducer Set, EnCor Probe Introducer
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: June 30, 2016
Received: July 1, 2016

Dear Ms. McCartney:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801) please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Christopher J. Ronk -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161805

Device Name

EnCor® MRI Introducer Set

EnCor® Probe Introducer

Indications for Use (Describe)

The EnCor® Introducer is used with the EnCor® biopsy probe to penetrate the breast under image guidance and provide a passageway through which a diagnostic biopsy of a breast may be performed.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based is as follows:

1. Submitter Information:

Applicant: SenoRx, Inc.
1625 West 3rd Street
Tempe, Arizona 85281

Contact: Sarah McCartney, B.S.
Senior Regulatory Affairs Specialist
sarah.mccartney@crbard.com
Phone: 480-638-2954
Fax: 480-449-2546

Date: June 30, 2016

2. Subject Device:

Device Trade Name: ENCOR[®] MRI Introducer Set
ENCOR[®] Probe Introducer

Common or Usual Name: Biopsy Guide, Trocar/Introducer

Classification: Class II

Classification Name: Instrument, Biopsy (Product Code KNW)

Review Panel: Gastroenterology/Urology

Regulation Number: 21 CFR 876.1075 (Gastroenterology-urology biopsy instrument)

3. Predicate Device:

The predicate device is the SenoRx, Inc. Introducers (K042098, cleared on August 19, 2004).

4. Summary of Change:

This submission details a change in the printing ink material used on the outer cannula of the subject device.

5. Device Description:

ENCOR[®] MRI Introducer Set

The ENCOR[®] MRI Introducer Set consists of a Trocar, Obturator, Cannula and Needle Guide Block. The Trocar, Obturator, and ENCOR[®] MRI probes can be used co-axially with the Cannula. When inserted in the cannula, the tip of the Obturator approximates the center of the sample aperture of the ENCOR[®] MRI Probe. Markings on the Cannula indicate the distance to the center of the ENCOR[®] MRI probe sample aperture.

ENCOR[®] Probe Introducer

The ENCOR[®] Probe Introducer is sterile, disposable and consists of an Introducer and Adapter. The ENCOR[®] Probe Introducer is used co-axially with the ENCOR[®] biopsy probe. The same Introducer allows for both tissue acquisition with an ENCOR[®] probe and subsequent marking of the biopsy site with GEL MARK ULTRACOR[®] Biopsy site marker.

6. Indications for Use of Device:

The ENCOR[®] Introducer is used with the ENCOR[®] biopsy probe to penetrate the breast under image guidance and provide a passageway through which a diagnostic biopsy of the breast may be performed.

7. Technological Comparison to Predicate Devices:

The technological characteristics of the subject device are substantially equivalent to those of the predicate device, in terms of following:

- Same intended use
- Same operating principal and method of action
- Same fundamental scientific technology
- Same design
- Same target population
- Same performance specifications
- Same packaging configuration
- Same sterility assurance level and method of sterilization

The subject devices and the predicate device are different in the following manner:

- Modifications to ink used in printing depth markings on cannula

8. Performance Testing Summary:

To verify that the device design met its functional and performance requirements, representative samples of each device underwent testing. Results of this testing demonstrate that the design outputs continue to meet the design inputs and user need requirements. Using the FDA guidance document, "Design Control Guidance for Medical Device Manufacturers," dated March 11, 1997, and internal risk assessment procedures, the following non-clinical tests were performed:

- Biocompatibility testing of ink used on cannulas (Cytotoxicity, Sensitization, Intracutaneous Reactivity, Pyrogen Testing)
- Functional testing after Accelerated Shelf Life and T=0 (Ink adhesion and ink adhesion IPA wiping)

The results demonstrate that the technological characteristics and performance criteria of the ENCOR[®] Introducers are comparable to the predicate device and that it performs as safely and as effectively as the legally marketed predicate device.

9. Conclusion:

The results of performance testing demonstrated the subject device is substantially equivalent to the legally marketed predicate device (K042098).