March 31, 2021

SenoRx, Inc.
Jessica Myer
Regulatory Affairs Specialist
1625 West 3rd Street
Tempe, Arizona 85251

Re: K210654
Trade/Device Name: EnCor Breast Biopsy Probe with Rinse Tube
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: March 4, 2021
Received: March 4, 2021

Dear Jessica Myer:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210654

Device Name
EnCor Breast Biopsy Probe with Rinse Tube

Indications for Use *(Describe)*
The EnCor™ Breast Biopsy Probe with Rinse Tube is indicated to acquire tissue for diagnostic sampling of breast abnormalities and saline rinse the tissue samples collected within the tissue chamber during a biopsy procedure. It is intended 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.

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.

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510(k) Summary
21 CFR 807.92

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
Phone:	480-597-8420
Fax:	312-949-0436
Contact:	Jessica Meyer, Regulatory Affairs Specialist
Date:	March 3, 2021

2. Subject Device:

Device Trade Name:	**EnCor™ Breast Biopsy Probe with Rinse Tube**
Common or Usual Name:	Breast Biopsy Probe
Classification Name:	Instrument, Biopsy (Product Code KNW)
Review Panel:	Gastroenterology/Urology
Regulation Number:	21 CFR 876.1075

3. Predicate Device:

EnCor™ Breast Biopsy Probe (K051158; May 16, 2005)

Reference Device: EnCor Enspire™ Breast Biopsy System Vacuum and Rinse Tubing Cassette (K111100; June 16, 2011)

4. Device Description:

The EnCor™ Breast Biopsy Probe with Rinse Tube is a handheld, single use, sterile (irradiation) biopsy probe used as part of a vacuum-assisted biopsy system (EnCor™ or EnCor Enspire™) and is intended to be used with ultrasound or stereotactic guidance. The probe is used for diagnostic sampling during a breast biopsy procedure. The device consists of a cutter/cannula

with a sharp trocar tip, housing, sample container, vacuum and rinse tubing, and a rinse sub-cassette. A stainless steel cutter acquires the tissue samples, which are transported by vacuum to the probe's sample container, where they may be rinsed with saline. The EnCor™ Breast Biopsy Probe with Rinse Tube is available in 7 gauge, 10 gauge, and 12 gauge, in both standard and vertical orientations for each gauge size.

5. Indications for Use of Device:

The EnCor™ Breast Biopsy Probe with Rinse Tube is indicated to acquire tissue for diagnostic sampling of breast abnormalities and saline rinse the tissue samples collected within the tissue chamber during a biopsy procedure. It is intended 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. Technological Comparison to Predicate Devices:

The technological characteristics of the subject device are the same as those of the predicate device, in terms of following:

- Intended Use
- Performance Characteristics
- Target Population
- Fundamental Scientific Technology
- Operating Principle (Mechanism of Action)
- Patient Contacting Materials
- Sterility Assurance Level and Method of Sterilization
- Packaging Configuration

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

- Indications for Use - The Indications for Use statement for the EnCor™ Breast Biopsy Probe with Rinse Tube is not identical to the predicate device. The difference in Indications for Use does not alter the intended use of the device as compared to the predicate and does not affect its safety and effectiveness as compared to the predicate.
- Directions for Use
- Precautions
- Integrated rinse tubing and sub-cassette assembly

7. Performance Testing Summary:

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated. Using the FDA Guidance document, "Design Control Guidance for Medical Device Manufacturers," dated March 11, 1997, and internal risk assessments procedures, the following non-clinical tests were performed:

- Cassette functionality and switch activation
- Vacuum testing
- Rinse testing
- Tensile testing
- Sub-cassette reliability
- Packaging validation

The results demonstrate that the technological characteristics and performance criteria of the EnCor™ Breast Biopsy Probe with Rinse Tube are comparable to the predicate device and that it performs as safely and as effectively as the legally marketed predicate device.

8. Conclusion:

The EnCor™ Breast Biopsy Probe with Rinse Tube is substantially equivalent to the legally marketed predicate device, the EnCor™ Breast Biopsy Probe (K051158).