October 27, 2023

SenoRx, Inc.
Kathryn Swanstrom
Regulatory Affairs Specialist II
1625 West 3rd Street
Tempe, Arizona 85251

Re: K233220
Trade/Device Name: EnCor Enspire™Breast Biopsy System (E4115, E4230); EnCor™ Breast Biopsy Driver (DRENCOR); EnCor™ MRI Breast Biopsy Driver (DRENCORMR); EnCor™ Breast Biopsy Driver Probes (ECP017G, ECP017GV, ECP0110G, ECP0110GV, ECP0112G, ECP0112GV); EnCor™ MRI Breast Biopsy Probes (ECPMR017G, ECPMR0110G, ECPMR0110GBT)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: September 28, 2023
Received: September 28, 2023

Dear Kathryn Swanstrom:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica Carr -S

Jessica Carr, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233220

Device Name
EnCor Enspire™ Breast Biopsy System (E4115, E4230); EnCor™ Breast Biopsy Driver (DRENCOR); EnCor™ MRI Breast Biopsy Driver (DRENCORMR); EnCor™ Breast Biopsy Probes (ECP017G, ECP017GV, ECP0110G, ECP0110GV, ECP0112G, ECP0112GV); EnCor™ MRI Breast Biopsy Probes (ECPMR017G, ECPMR0110G, ECPMR0110GBT)

Indications for Use *(Describe)*
The EnCor Enspire™ Breast Biopsy System is indicated to acquire breast tissue for histologic examination with partial or complete removal of the abnormality.

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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EnCor Enspire™ Breast Biopsy System, Drivers, and Probes
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 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant:	SenoRx, Inc. 1625 West 3rd Street Tempe, Arizona 85281
Phone:	602-830-5623
Fax:	312-949-0436
Contact:	Kathryn Swanstrom
Date	October 27th, 2023

Subject Device Name:

Device Trade Name:	**EnCor Enspire™ Breast Biopsy System, Drivers, and Probes**
Common or Usual Name:	Biopsy Instrument
Classification:	Class II
Regulation:	21 CFR 876.1075
Review Panel:	Gastroenterology/Urology
Product Code:	KNW

Predicate Devices:

EnCor Enspire™ Breast Biopsy System (K111100, cleared 16 June 2011)

EnCor™ Probes (K093512, cleared 20 November 2009)

EnCor™ Drivers (K093512, cleared 20 November 2009)

Device Description:

The EnCor Enspire™ Breast Biopsy System provides control operations for specialized biopsy instruments intended to acquire tissue samples of suspected breast abnormalities for diagnostic sampling. The EnCor Enspire™ Breast Biopsy System may be utilized with ultrasound, stereotactic, or MRI imaging guidance during the biopsy procedure. The EnCor Enspire™ Breast Biopsy System may be used with the EnCor™ Probes and EnCor™ Drivers. The EnCor Enspire™ Breast Biopsy System is reusable and provided non-sterile.

The EnCor™ Probe is a handheld biopsy probe used as part of a vacuum-assisted breast biopsy system. The EnCor™ Probe is meant to be used with an EnCor Enspire™ Breast Biopsy System or an EnCor™ Breast Biopsy System. The EnCor™ Probe is provided sterile and is intended for single use.

The EnCor™ Drivers are handheld units for ultrasound guided breast biopsies and for mounting on stereotactic platforms using adapters. The EnCor™ Drivers are reusable and provided non-sterile.

Indications for Use of Device:

The EnCor Enspire™ Breast Biopsy System is indicated to acquire breast tissue for histologic examination with partial or complete removal of the abnormality.

Comparison to Predicate Device:

The technological characteristics of the subject device are the same as those of the predicate device.

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

- Modifications to the Indication for Use Statement

As compared to the predicate indications, the additional medical practice guidelines on management of breast lesions based on the results of the diagnosis have been removed from the indications for use statement. Instead, updated precautionary language on medical practice

guidelines is included in the warnings section of the instructions for use. This allows for a more concise indications for use statement that focuses on specifying the disease or condition the device will diagnose, treat, prevent, cure or mitigate, per CFR 814.20(b)(3)(i). These modifications are clerical in nature. There are no changes to the anatomical location (breast), condition (breast abnormality), patient population (patient with a breast abnormality), or clinical context or setting (hospital/medical facility). There are no changes to the potential complications of the device's use, the equipment required for use of the device, the directions for use of the device, nor the contraindications for the device use. The device continues to be indicated for the acquisition of breast tissue samples for histologic examination with partial or complete removal of the abnormality, which is the critical medical application of the device for patients in clinical practice. Therefore, there are no changes to any "intended therapeutic, diagnostic, prosthetic, or surgical use of the device" as prescribed within 21 CFR 807.92(a)(5), and no new concerns are raised by these modifications for the device's safety and effectiveness when used as labeled.

Performance Data:

The change to the Indications for Use described in this submission does not affect the design of the device and no new or increased risks have been identified, therefore additional bench performance testing was not warranted.

Conclusion:

The subject devices, the EnCor Enspire™ Breast Biopsy System, Drivers and Probes, are substantially equivalent to the legally marketed predicate devices.