August 20, 2018

Medical Park CO., LTD
% Mr. Dave Kim, MBA
Medical Device Regulatory Affairs
8310 Buffalo Speedway
Houston, Texas 77025

Re: K171890
Trade/Device Name: BEXCORE Breast Biopsy System, Biopsy Needle
BXC135, BXC140, BXC145 Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW, FCG
Dated: July 16, 2018
Received: July 23, 2018

Dear Mr. Kim:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171890

Device Name
BEXCORE Vacuum Assisted Breast Biopsy System;
BXC135, BXC140, BXC145 Biopsy Needle

Indications for Use *(Describe)*

The BEXCORE Vacuum Assisted Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities.
- It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.
- It is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality.

The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or 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. In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g. fibroadenoma, fibrocystic lesion), the BEXCORE Vacuum Assisted Breast Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. 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.

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510(k) Summary

Date 510k summary prepared: August 16, 2018

I. SUBMITTER

Submitter's Name	Medical Park Co., Ltd.
Submitter's Address	#601/623/624/901, Knowledge-Industry Center, BundangSuji U-Tower, 767, Sinsu-ro, Suji-gu Yongin-si, Gyeonggi-do, Korea
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Official Correspondent	Mtech Group Dave Kim, MBA, President davekim@mtech-inc.net
Address	8310 Buffalo Speedway, Houston, TX 77025
Telephone	+713-467-2607

II. DEVICE

Trade/proprietary Name	BEXCORE Vacuum Assisted Breast Biopsy System; BXC135, BXC140, BXC145 Biopsy Needles
Common or Usual Name	Vacuum Assisted Breast Biopsy System & Needle
Regulation Name	Gastroenterology-urology biopsy instrument
Regulation Number	21 CFR 876.1075 (Product Code: KNW, FCG)
Regulatory Class	Class II

III. PREDICATE DEVICE

Primary Manufacturer	SenoRx, Inc
Device Name	EnCor Breast Biopsy System
510(k) Number	K093512(Decision Date – Nov 20, 2009)
Regulation Name	Gastroenterology-urology biopsy instrument
Regulation Number	21 CFR 876.1075 (Product Code: KNW)
Regulatory Class	Class II

IV. REFERENCE DEVICE

Primary Manufacturer	PFM Medical, Inc
Device Name	Safety Biopsy Needle System
	Safety Biopsy Needle and Safety Coaxial Needle
510(k) Number	K140137(Decision Date – March 25, 2014)
Regulation Name	Gastroenterology-urology biopsy instrument
Regulation Number	21 CFR 876.1075 (Product Code: FCG)
Regulatory Class	Class II

V. DEVICE DESCRIPTION

BEXCORE Vacuum-Assisted Breast Biopsy (hereinafter referred to as VABB) system is 'a set of equipment used for biopsy' composed of a sterilized disposable needle probe unit (hereafter Probe) and an electronic system unit. The electronic system unit consists of a driver and a main controller box (hereafter Main Body for main controller box). A biopsy needle-BXC135, BXC140, BXC145 are the Probes approved separately-is mounted on a driver, and then inserted into a breast. The inserted biopsy needle, powered by the motor in the Main Body of BXS100F, could be rotated or moved forward/backward to cut affected tissue of the breast. The cut tissues are pulled out by vacuum pressure to a filter mesh of Probe connected to the vacuum suction unit of BXS100F's Main Body. At the moment of completing tissue cut, the air supplied from a Main Body to the front part of the biopsy needle makes easy to discharge the cut tissue smoothly.

VI. INDICATIONS FOR USE:

The BEXCORE Vacuum-Assisted Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities.

- It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

- It is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality.

The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or 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. In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g. fibroadenoma, fibrocystic lesion), the BEXCORE Vacuum-Assisted Breast Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. 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.

VII. Substantial Equivalence

BEXCORE Vacuum Assisted Breast Biopsy System is substantially equivalent to EnCor (K093512). The following comparison table is presented to demonstrate substantial equivalence.

	SUBJECT DEVICE	Predicate 1	Remarks
510(k) Number	K171890	K093512	-
Device Trade(Brand) Name	BEXCORE Vacuum-Assisted Breast Biopsy System BXC135, BXC140, BXC145 Biopsy Needles	EnCor Breast Biopsy System	-
Common Name	Biopsy System	Biopsy System	-
Manufacturer	MEDICAL PARK CO., Ltd..	SenoRx, Inc.	-
Intended Use	The BEXCORE Vacuum-Assisted Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. - It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. - It is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality. The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or 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. In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g. fibroadenoma, fibrocystic lesion), the BEXCORE	The EnCor Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. - It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. - It is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality. The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or 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. In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g. fibroadenoma, fibrocystic lesion), the EnCor	Same

	be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. 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	be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. 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	
needle, cannula(s),	8G, 10G and 12G	7G, 10G and 12G	Same
jaw size	5mm, 10mm, 15mm, 20mm	10mm, 20mm	Different
mode of action	Vacuum-assisted device to remove breast tissue, single puncture and multiple samples, brush rotation, suction scraping, for use with ultrasound	Vacuum-assisted device to remove breast tissue, single puncture and multiple samples, brush rotation, suction, scraping, for use with ultrasound	Same
electrical	100~120VAC 6A, 50/60Hz, 460VA	110-120V~, 10A, 50/60Hz 220-240V~, 10A, 50/60Hz	Similar
Material come into patient contact : Needle	Needle: stainless steel	Needle: stainless steel	Same
vacuum pressure	-LOW: -15kPa ~ -35kPa -MID: -35kPa ~ -55kPa -HIGH: -55kPa ~ -80kPa	-82.4kPa	Different
method of placement; and other related information	A biopsy of breast tissue must be taken only at the position diagnosed and determined based on the ultrasound image. Device operate with foot switches and driver(holster).	A biopsy of breast tissue must be taken only at the position diagnosed and determined based on the ultrasound image. Device operate with foot switches and driver(holster).	Same
Single Use Component	Vacuum- Assisted Breast Biopsy Needle	Vacuum- Assisted Breast Biopsy Needle	Same
Reusable Component	Suction canister, Hand driver, Foot switch	Suction canister, Hand driver, Foot switch	same
Electrical	120V, 60Hz, 5A, 460VA	Free voltage	Same

VIII. DESCRIPTION THE DIFFERENCES OF SUBJECT DEVICE AND PREDICATE DEVICE

BEXCORE Vacuum Assisted Breast Biopsy System has the same indications for use. It shows equivalent specifications with the predicate devices in most of parameters. The main difference is that the subject device offers different Jaw size and has a lower vacuum pressure range than the predicate devices.

Despite the differences above, the performance test results submitted in this 510k shows that the subject device is substantially equivalent to the predicate devices in safety and effectiveness.

IX. Performance Testing

Performance testing of the Bexcore Vacuum Assisted Biopsy Needle System was conducted in accordance with the following international standards:
"Guidance on Premarket Notification [51 0(k)] for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA. 03/01/1995
"Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology"
"AAMI/ANSI/lSO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified Safety & ISO 10993 Test Profile
* AAMI/ANSI/lSO 1 0993-7:-2008, Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Results
* AAMI/ANSI/ISO 11135:2007, Sterilization of Healthcare Products Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
* ISO 14971:2007, Medical Devices - Risk Management for Medical Devices.

Pyrogen Test and Endotoxin Test were conducted based on "ISO 10993-11: 2006, Information on material mediated pyrogens which is FDA recognized standard (recognition no: 2-176).

The EMC and Electrical safety tests are conducted based on the currently FDA-recognized version of standards.
IEC 60601-1-2: 2007 is FDA recognized IEC standard (Recognition No: 19-1).
IEC 60601-1 Electrical Safety Test report contains the US National Differences – Differences according to US National standard ANSI/AAMI ES6060-1-: 2005 / A2: 2010.

Furthermore, the following non-clinical bench tests were performed on the BEXCORE Biopsy Needle System and compared to the predicate device.
* Ability to extract a biopsy tissue sample
* Average Tissue Length
* Edge of Cut Sample Evaluation
* Average Tissue Weight
* Multiple Sample Operation of the BEXCORE Biopsy Needle
* Vacuum Pressure
* Safety Feature (Cover) of the BEXCORE Biopsy Needle
* Force to Arm the BEXCORE Biopsy Needle
* Force to Advance the BEXCORE Biopsy Needle
* BEXCORE Biopsy Needle Obstruction Test

* Tissue sample dimensions, firmness for combinations of jaw size, vacuum settings

All of these performance tests demonstrate the device performs according to its intended use and meets the performance specifications.

X. Summary

Based on the indications for use and safety and performance testing, the BEXCORE Vacuum Assisted Biopsy Needle System meets the requirements that are considered for its intended use and is substantially equivalent in design materials, sterilization, and indications for use. The conclusions drawn from the nonclinical tests demonstrate that the device is as safe and effective as the legally marketed device.