DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Corbin Clinical Resources, LLC
% Mr. Kenneth Kleinhenz
Regulatory Affairs Consultant
12234 Williams Road
CUMBERLAND MD 21502

August 1, 2016

Re: K160414
Trade/Device Name: PrecisionPoint Biopsy Needle Guide
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: July 1, 2016
Received: July 8, 2016

Dear Mr. Kleinhenz:

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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K160414

Device Name
PrecisionPoint Biopsy Needle Guide

Indications for Use *(Describe)*
The intended use of the Perineologic PrecisionPoint™ Biopsy Needle Guide when used in conjunction with a BK ProFocus 2202 ultrasound system and attached to the ultrasound system's transrectal transducer, is to facilitate proper needle placement to access anatomical structures.

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.

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ADMINISTRATIVE INFORMATION

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Regulatory Affairs Consultant
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DEVICE NAME

Classification Name: Diagnostic Ultrasonic Transducers Accessory

Trade/Proprietary Name: PrecisionPoint Biopsy Needle Guide

ESTABLISHMENT REGISTRATION NUMBER

This is the first Corbin Clinical Resources, LLC device applications to FDA. Corbin Clinical Resources, LLC will register and pay the fee within 30 days of FDA's clearance of this device.

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 892.1570, Accessories to Diagnostic Ultrasonic Transducers are devices intended for use in/with diagnostic ultrasonic medical devices and may include transmission media for acoustically coupling the transducer to the body surface, such as acoustic gel, paste, or a flexible fluid container. These devices are classified as Class II. Diagnostic Ultrasonic Transducers have been assigned Product Code ITX.

INTENDED USE

The intended use of the Perineologic PrecisionPoint™ Biopsy Needle Guide when used in conjunction with a BK ProFocus 2202 ultrasound system and attached to the ultrasound system's transrectal transducer, is to facilitate proper needle placement to access anatomical structures.

DEVICE DESCRIPTION

Design Characteristics

The PrecisionPoint Biopsy Needle Guide is a sterile, single use, disposable, polymeric needle guide containing 2 pieces of molded plastic (carriage and rail/clamp). The PrecisionPoint Biopsy Needle Guide is pressed / placed onto the skin in the region overlying the area to be biopsied. The PrecisionPoint Biopsy Needle Guide holds both the ultrasound probe and the needle guide in place relative to each other while the ultrasound-guided biopsy is being preformed. The PrecisionPoint Biopsy Needle Guide is an assembly of 3 unique polymeric components: carriage, rail, and clamp. The carriage component slides onto the rails to create an assembly that can hold and maintain the relative position of an ultrasound probe and a needle guide at the same time.

The clamp component is a ring shaped structure with 2 opposing rectangular handles at the bottom of the ring that contain a male flange that is designed to mate with the opposing female cavern. The male flange has ridges on the bottom of the flange while the female cavern has ridges on the top of the cavern, creating an adjustable locking mechanism in which the next row of ridges align and lock as the male flange advances. The advancement of the male flange into the opposing female cavern creates a ring with decreased and smaller circumference that imposes increased pressure on a cylindrical ultrasound probe positioned within the ring of the clamp component. The clamp component is designed to accommodate a cylindrical style transrectal ultrasound transducer (0.7" to .85" diameter BK #8658 or equivalent) associated with a BK ProFocus ultrasound system cleared under K043524.

The carriage component has 5 equal holes to accommodate a 14 gauge needle and may contain holes of equal or various diameters from 14 gauge to 20 gauge. The 5 needle holes are equally spaced approximately 5cm apart and may be spaced closer or farther apart depending on the diameter of the holes. The number of needle holes may vary from as few as 1 to as many as 8. The dimensions of the fully assembled PrecisionPoint Biopsy Needle Guide are approximately 5.5cm long, 7cm tall, and 4.5cm wide.

PERFORMANCE TESTING

The PrecisionPoint Biopsy Needle Guide was tested against the following standards: ISO 11135-1:2007 - Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices, ISO 10993-1 - Biological Evaluation of Medical Devices, and ANSI/AAMI/ISO 11607–1 Packaging for Terminally Sterilized Medical Devices Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging, ANSI/AAMI/ISO 11607–2 Packaging for Terminally Sterilized Medical Devices Part 2: Validation Requirements for Forming, Sealing and Assembly Process.

EQUIVALENCE TO MARKETED PRODUCT

Corbin Clinical Resources, LLC PrecisionPoint Biopsy Needle Guide shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: Sonosite iLook 25 Needle Guide Attachment and Bracket Assembly; Class II medical devices that were cleared for marketing in the United States under K030064.

Indications For Use

The PrecisionPoint Biopsy Needle Guide shares indications for use principles with the Sonosite iLook 25 Needle Guide Attachment and Bracket Assembly predicate devices (K030064) as both devices are indicated for use in the same minimally invasive procedures involving soft tissue biopsies. Moreover, the PrecisionPoint Biopsy Needle Guide shares indications for use language with the Sonosite iLook 25 Needle Guide Attachment and Bracket Assembly (K030064) predicate devices.

Design and Materials

The material and design principles of the PrecisionPoint Biopsy Needle Guide and the Sonosite iLook 25 Needle Guide Attachment and Bracket Assembly predicate device (K030064) are substantially equivalent, consisting of sterile, single-use, non-invasive devices fabricated from a medical grade polymeric material. All devices also share the common design principles of attaching to an ultrasound transducer and holding a biopsy needle.

The PrecisionPoint Biopsy Needle Guide and the Sonosite iLook 25 Needle Guide Attachment and Bracket Assembly predicate device (K030064) are substantially equivalent as the devices are fabricated from substantially equivalent, medical-grade, polymeric materials.

The PrecisionPoint Biopsy Needle Guide and the Sonosite iLook 25 Needle Guide Attachment and Bracket Assembly predicate device (K030064) are substantially equivalent as they share substantially equivalent design principles of accepting a biopsy needle or needle guide and attaching to an ultrasound transducer.

The PrecisionPoint Biopsy Needle Guide and the Sonosite iLook 25 Needle Guide Attachment and Bracket Assembly predicate device (K030064) are substantially equivalent as they share substantially equivalent design principles of being non-invasive devices that are placed onto the patient's skin in preparation for guiding a biopsy procedure involving a biopsy needle.