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

September 22, 2016

Corbin Clinical Resources, LLC
Kenneth K. Kleinhenz
Regulatory Affairs Consultant
12234 Williams Road
Cumberland, MD 21502

Re: K160423
Trade/Device Name: Perineologic Access Needle
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: FCG
Dated: August 15, 2016
Received: August 17, 2016

Dear Kenneth K. Kleinhenz:

This letter corrects our substantially equivalent letter of September 2, 2016.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially (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 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" (21CFR 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,

For Division

Douglas Silverstein -S
2016.09.22 11:06:41 -04'00'

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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)*
K160423

Device Name
Perineologic Access Needle

Indications for Use *(Describe)*
The Perineologic Access Needle is intended for use as a guiding needle in obtaining core biopsy samples from soft tissue and tumors of such organs as liver, kidney, spleen, lymph nodes, prostate, lung and various soft tissue lesions.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DATE OF PREPARATION 02 SEPTEMBER 2016

ADMINISTRATIVE INFORMATION

Manufacturer Name: Corbin Clinical Resources, LLC
12234 Williams Road
Cumberland, MD 21502
Tel: 301-724-0132
Fax: 301-759-5874

Official Contact: Kenneth K. Kleinhenz
Regulatory Affairs Consultant
Telephone (858) 458-0900
Fax (858) 458-0994

DEVICE NAME

Classification Name: Biopsy Needle Kit

Trade/Proprietary Name: Perineologic Access Needle

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 876.1075, Gastroenterology-urology biopsy instruments are devices used to remove, by cutting or aspiration, a specimen of tissue for microscopic examination. These devices are classified as Class II. Gastroenterology-urology biopsy instruments have been assigned product code FCG.

INDICATIONS FOR USE

The Perineologic Access Needle is intended for use as a guiding needle in obtaining core biopsy samples from soft tissue and tumors of such organs as liver, kidney, spleen, lymph nodes, prostate, lung and various soft tissue lesions.

DEVICE DESCRIPTION

Design Characteristics

The Perineologic Access Needle is a sterile, single use, disposable, hollowed/tubular, stainless steel needle that is sharpened at one end and blunt on the opposing end while containing a polymeric hub with a female luer-lock style fitting to accept a male luer lock syringe. The polymeric hub contains a female luer fitting on the proximal end, a protruding, elongated rectangle for gripping, and a distal circumferential tubular lip that protrudes approximately 1 cm along the axis of the stainless steel needle. The protruding rectangle in the middle of the polymeric hub has 2 opposing and equal sides in the shape of a tapered rectangle containing ribs for gripping. The remaining 2 sides of the tapered rectangle are hollowed.

The Perineologic Access Needle is provided in various lengths and diameters as required for particular biopsy procedures. The Perineologic Access Needle is provided in lengths ranging from 7cm to 20cm and inner diameters ranging from 14 gauge to 20 gauge.

PERFORMANCE TESTING

The Perineologic Access Needle was tested against the following standards: ANSI/AAMI/ISO 11135:2014 - Sterilization of Health Care Products - Ethylene Oxide - 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 Perineologic Access Needle shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to the following devices: Bard TrueGuide™ Coaxial Biopsy Needle Guide (K936194) and the PFM Medical Biopsy Needle System (K140137); Class II medical devices that were cleared for marketing in the United States under K936194 and K140137 respectively.

Design and Materials

The material and design principles of the Perineologic Access Needle and the predicate devices [Bard TrueGuide™ Coaxial Biopsy Needle Guide (K936194) and the PFM Medical Biopsy Needle System (K140137)] are substantially equivalent, consisting of sterile, single-use devices fabricated from a medical grade polymeric material and stainless steel. All devices also share the common design principles of being composed of materials that are intended for transient use with soft tissues.

The Perineologic Access Needle and the predicate devices [Bard TrueGuide™ Coaxial Biopsy Needle Guide (K936194) and the PFM Medical Biopsy Needle System (K140137)] are substantially equivalent as the needles are all fabricated from substantially equivalent, medical-grade, stainless steel and the opposite end of the needle is fabricated from substantially equivalent, medical-grade, polymeric material to attached to a polymeric syringe.

The Perineologic Access Needle and the predicate devices [Bard TrueGuide™ Coaxial Biopsy Needle Guide (K936194) and the PFM Medical Biopsy Needle System (K140137)] are substantially equivalent as they all share the same design of a polymeric female luer lock hub that is designed to attach to a luer style syringe.

The Perineologic Access Needle and the predicate devices [Bard TrueGuide™ Coaxial Biopsy Needle Guide (K936194) and the PFM Medical Biopsy Needle System (K140137)] are substantially equivalent as they all share the same design of a hollowed, stainless steel tube sharpened at one end and blunt at the other end with a polymeric hub attached to the blunt end.

The Perineologic Access Needle and the predicate devices [Bard TrueGuide™ Coaxial Biopsy Needle Guide (K936194) and the PFM Medical Biopsy Needle System (K140137)] are substantially equivalent as they all share the same design principals of puncturing tissue to guide the position of a biopsy needle and to create a passage for another needle of smaller diameter to pass through and obtain a biopsy sample.