DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

December 5, 2014

IZI Medical Products
Qiang Cao
Manager of Quality Assurance and Regulatory Affairs
5 Easter Court, Suite J
Owings Mills, MD 21117

Re: K140705
Trade/Device Name: Navigable Brain Biopsy Cannula Set
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 4, 2014
Received: November 6, 2014

Dear Mr. Qiang Cao,

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 and Part 809); 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 and Part 809), 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,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine 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)*
K140705

Device Name
IZI Navigable Brain Biopsy Cannula Set

Indications for Use *(Describe)*
The BL Navigated Biopsy Needle is indicated for stereotactic biopsy of cranial tissue using BrainLab AG's VectorVision navigation system. The Navigated Biopsy Needle is a pre-sterilized, single-use, side-cutting needle where the cutting action is achieved by rotation of an inner cannula within an outer cannula.

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

510(k) Owner

IZI Medical Products LLC

5 Easter Court, Suite J

Owings Mills, MD 21131

Phone: (410) 594-9403

Fax: (410) 594-0540

Date Summary Prepared: July 25, 2014

Device Name

Trade Name: BL Navigated Biopsy Needle

Common or Usual Name: Stereotactic Biopsy Needle

Classification Name: Neurological Stereotactic Instrument (21 CFR 882.4560)

Product Code: HAW (Neurological Stereotactic Instrument)

Predicate Device

VectorVision Frameless Biopsy System (K012564)

Medtronic Biopsy Needle (K971247)

Device Description

BL Navigated Biopsy Needle contains a calibrated biopsy cannula that is used with a compatible image guided surgery navigation system in stereotactic biopsy of cranial tissue. The device is compatible with specified BrainLab navigation systems (see intended use section below). Like the predicate device, the BL Navigated Biopsy Needle is a pre-sterilized, single-use, stainless steel device and uses a side-cutting cannula where the cutting action is achieved by rotation of an inner cannula within an outer cannula.

BL Navigated Biopsy Needle's components include a navigable biopsy cannula, a biopsy cannula stop with screw, a stop adjustment tool and an aspiration tube.

Indications for Use

The BL Navigated Biopsy Needle is indicated for stereotactic biopsy of cranial tissue using BrainLab AG's VectorVision navigation system. The Navigated Biopsy Needle is a pre-sterilized, single-use, side-cutting needle where the cutting action is achieved by rotation of an inner cannula within an outer cannula.

Patient Population

The device is intended for use in patients undergoing stereotactic cranial tissue biopsy procedures.

Environment of Use

The device is intended for use by a trained healthcare professional in a healthcare facility.

Summary of Technological Characteristics

The BL Navigated Biopsy Needle contains a navigable biopsy cannula constructed with an inner and outer stainless steel needle with a side-cutting window, a plastic hub and a set of retro-reflective discs. The reflective discs allow the device to be registered with BrainLab navigation systems and to be visible during a biopsy procedure. The Set also contains a biopsy cannula stop with screw, a stop adjustment tool and an aspiration tube.

The BL Navigated Biopsy Needle and the predicated devices, the BrainLab Biopsy Needle Type A (K012564) and Medtronic Biopsy Needle (K971247), are based on the following same technological elements: material, construction, registration and tracking method and cutting actions. The table below summarizes the comparison of technological characteristics among the subject device and predicate devices.

Technical Characteristics	Subject Device (K140705)	BrainLab Biopsy Needle Type A	Medtronic Biopsy Needle
Needle Material	Stainless steel	Stainless steel	Stainless steel
Biopsy Needle Construction	Inner and outer cannula	Inner and outer cannula	Inner and outer cannula
Biopsy Cutting Action	Side cutting	Side cutting	Side cutting

	window	window	window
Registration and Tracking method	retro-reflective material	retro-reflective material	retro-reflective material
Needle Dimension (diameter)	2.1 mm	1.8 mm	2.1 mm

There are minor differences in needle dimension between the devices.

Summary of Performance Testing

Bench testing was conducted to demonstrate that the BL Navigated Biopsy Needle performs as intended and is substantially equivalent to the predicate device. Tissue extraction testing was conducted to verify the ability of the device to sample tissue. Navigation testing was conducted to verify the compatibility and accuracy of the device with the specified navigation systems. Real-time shelf life testing was conducted to verify that there was no change in visual attributes, dimensional characteristics, or tensile strength after 5 years real time storage. These studies verify that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device identified above.

The biocompatibility evaluation for the BL Navigated Biopsy Needle was conducted in accordance with ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro Cytotoxicity and ANSI/AAMI ST72:2011 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing. The battery of testing included the following tests:

- Cytotoxicity
- Pyrogen Testing

The patient contacting components of the Navigated Biopsy Needle are the outer and inner cannula. Patient contact time of the device is less than 24 hours. The outer and inner cannula are both made from AISI 304 stainless steel.

Summary

In summary, the non-clinical data support the safety of the device and the hardware verification and validation testing demonstrate that the IZI Navigated Biopsy Needle, used with BrainLab Vector Vision navigation system, should perform as intended in the specified use conditions.