DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 13, 2015

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

Re: K143241
Trade/Device Name: MDT Navigable Brain Biopsy Cannula
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: March 10, 2015
Received: March 12, 2015

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)*
K143241

Device Name
MDT Navigable Brain Biopsy Cannula

Indications for Use *(Describe)*
The MDT Navigable Brain Biopsy Cannula is for use in stereotaxic biopsy of cranial tissue. The MDT Navigable Brain Biopsy Cannula is a pre-sterilized, single-use, sidecutting cannula where the cutting action is achieved by rotation of an inner cannula within an outer cannula. The device is compatible with Medtronic's StealthStation® Image Guided Surgery System.

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

I. Submitter

IZI Medical Products LLC
5 Easter Court, Suite J
Owings Mills, MD 21117

Phone: (410) 594-9403
Fax: (410) 594-0540

Contact Person: Qiang Cao
Date Prepared: April 7, 2015

II. Device

Trade Name: MDT Navigable Brain Biopsy Cannula

Common or Usual Name: Stereotaxic Biopsy Needle

Classification Name: Neurological Stereotaxic Instrument (21 CFR 882.4560)

Product Code: HAW (Neurological Stereotaxic Instrument)

III. Predicate Devices

Medtronic Biopsy Needle (K971247)

IV. Device Description

The MDT Navigable Brain Biopsy Cannula contains a calibrated biopsy cannula that is used with a compatible image guided surgery navigation system in stereotaxic biopsy of cranial tissue. The device is compatible with Medtronic's StealthStation® Image Guided Surgery System. Like the predicate devices, both devices are pre-sterilized, single-use, stainless steel devices and use a side-cutting cannula where the cutting action is achieved by rotation of an inner cannula within an outer cannula.

The MDT Navigable Brain Biopsy Cannula components include a navigable biopsy cannula, a biopsy cannula stop with screw, a stop adjustment tool and an aspiration tube.

V. Intended Use of the Device

The MDT Navigable Brain Biopsy Cannula is for use in stereotaxic biopsy of cranial tissue. The MDT Navigable Brain Biopsy Cannula is a pre-sterilized, single-use, side-cutting cannula where the cutting action is achieved by rotation of an inner cannula within an outer cannula. The device is compatible with Medtronic's StealthStation® Image Guided Surgery System.

Patient Population
The device is intended for use in patients undergoing stereotaxic brain biopsy procedures.

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

VI. Summary of Technological Characteristics

The MDT Navigable Brain Biopsy Cannula contains a navigable biopsy cannula constructed with an inner and outer stainless steel cannula with a side-cutting window, a plastic hub and a set of retro-reflective elements. The reflection elements allow the cannula to be registered with the Medtronic's StealthStation® Image Guided Surgery System and to be visible during a biopsy procedure. The Product also contains a biopsy cannula stop with screw, a stop adjustment tool and an aspiration tube.

The MDT Navigable Brain Biopsy Cannula is comparible to the Medtronic Biopsy Needle Kit (K971247) regarding its intended use, functional and dimensional characteristics, and overall performance. Minor dimensional differences between the devices have no impact on safety or effectiveness.

Technical Characteristics	**Subject Device (K143241)**	**Medtronic Biopsy Needle (K971247)**	**Comparison**
Needle/Cannula Material	Stainless steel (AISI 304)	Stainless steel (AISI 304)	Identical
Biopsy Needle/Cannula Construction	Inner and outer cannula	Inner and outer cannula	Identical
Biopsy Cutting Action	Side cutting window	Side cutting window	Identical

Registration and Tracking Method	Retro-reflective material	Retro-reflective material	Identical
Compatible IGS	Medtronic StealthStation®	Medtronic StealthStation®	Identical
Needle Dimension (diameter)	2.1 mm	2.1 mm	Identical

VII. Summary of Performance Testing

Bench testing was conducted to demonstrate that the MDT Navigable Brain Biopsy Cannula performed as intended and is comparable 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 of the devices with the Medtronic StealthStation® IGS systems. These studies verify that the device is comparable with the legally marketed predicate device identified above.

VIII. Conclusion

The non-clinical data support the safety of the device and the hardware verification and validation demonstrate that the MDT Navigable Brain Biopsy Cannula device should perform as intended in the specified use conditions. The non-clinical data demonstrate that the MDT Navigable Brain Biopsy Cannula device performs comparably to the predicate device that is currently marketed for the same intended use.