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

March 20, 2015

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

Re: K142344
Trade/Device Name: Disposable Passive Accessory for Medtronic StealthStation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: February 16, 2015
Received: February 18, 2015

Dear Mr. 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); 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
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 on last page.

510(k) Number *(if known)*
K142344

Device Name
Disposable Passive Accessory for Medtronic StealthStation® System

Indications for Use *(Describe)*
The Disposable Passive Accessory is intended to be used for anatomy palpation and registration in image guided surgeries with Medtronic StealthStation® System. The device is sterile and designed for single use.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. SUBMITTER

IZI Medical Products LLC
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Phone: (410) 594-9403
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Contact Person: Qiang Cao
Date Prepared: March 19, 2015

II. DEVICE

Name of Device: Disposable Passive Accessory for Medtronic StealthStation® System
Common or Usual Name: Disposable Passive Accessory
Classification Name: Neurological Stereotaxic Instrument (21 CFR 882.4560)
Regulatory Class: II
Product Code: HAW (Neurological Stereotaxic Instrument)

III. PREDICATE DEVICE

StealthStation® System Update (K050438)
Spherz® (Passive Reflective Marker) (K022074)

IV. DEVICE DESCRIPTION

The IZI Disposable Passive Accessory contains one disposable point probe mounted with five passive reflective sphere markers, as well as ten additional passive reflective sphere markers. The Disposable Passive Accessory is intended to be used for anatomy palpation and registration in image guided surgeries with the Medtronic StealthStation® system. The device is sterile and designed for single use.

The Disposable Passive Accessory provides a single-use alternative to Medtronic reusable parts. The Disposable Passive Accessory is constructed by a dimension stable thermoplastic handle where five passive reflective sphere markers are mounted on, with a stainless steel tip that is used to register and locate patient anatomical structure in an image guided surgery using the Medtronic StealthStation® System. The permanently mounted passive reflective spheres are at the same three dimensional locations as the Medtronic predicate product. In an IGS procedure, the two cameras of the StealthStation® captures the reflective light from the five sphere markers

for the System to calculate and determine the location of the stainless tip and the position of the probe.

V. INDICATIONS FOR USE

The Disposable Passive Accessory is intended to be used for anatomy palpation and registration in image guided surgeries with Medtronic StealthStation system. The device is sterile and designed for single use.

The indication for use statement for the Disposable Passive Accessory is very similar to the labeled indication for use of the Medtronic Passive Planar Probe, however, the predicate device is an accessory part of the Medtronic StealthStation System. The Medtronic 510(k) K050438 indication for use emphasizes the System and applicable procedures, and the specific indication of use for each accessory part is not clearly stated in the 510(k). The minor difference of the subject device and the predicate device is that the subject device is single use and provided to the user as a sterile device. This does not affect the intended surgical use of the device. The IZI Spherz are a component part of the subject device. The subject device uses the Spherz within the scope of indication for use of the Spherz.

Patient Population
The device is intended for use in patients undergoing stereotactic surgery.

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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The IZI Disposable Passive Accessory contains a disposable passive probe where five passive reflective markers are mounted, as well as ten additional passive reflective markers. The five passive reflective markers mounted on the probe allow the probe to be recognized and registered in the StealthStation system. The predicate devices are the Medtronic StealthStation® System and the Medtronic Passive Planar Probe (Medtronic part number 960-556).

Technical Characteristics	**IZI Disposable Passive Accessory (subject device)**	**Medtronic StealthStation® and Passive Planar Probe (K050438)**	**Comparison of Technology**
Physical dimensions and 3D locations of marker post relative to probe tip	Same as the Medtronic Passive Planar Probe	Medtronic Passive Planar Probe	Identical

Probe tip material	Stainless steel (303 stainless steel)	Stainless steel (630 stainless steel)	Both materials are stainless steel
Passive Reflective Marker	Identical to Spherz, permanently mounted onto the probe post	Medtronic predicate does not include the passive reflective markers. The same passive reflective markers are provided separately and mounted manually by user.	Identical
Single Use or Reusable	Single use	Reusable	Subject Device is for single use
Sterile	Sterile	Not sterile	Subject Device is provided as sterile

The Disposable Passive Accessory is comparable to the Medtronic StealthStation and reusable accessory (K050438) regarding its intended use, functional and dimensional characteristics, and overall performance. Minor differences between the disposable devices and reusable device have no impact on safety or effectiveness.

Biocompatibility Profile – The device is an externally communicating, tissue contacting device with limited patient contact. The patient contact time is less than 24 hours. The product is made from materials and components were known to be biocompatible or have a history of being used in similar medical devices. The product is made in a controlled manufacture process that no cleaning agent or chemicals are used. To ensure the safety of the product, we have performed a cytotoxicity test. The test confirmed that the product does not cause any cell lysis or toxicity.

VII. PERFORMANCE DATA

Two non-clinical bench tests were conducted to demonstrate that the IZI Disposable Passive Accessory performs as intended and is comparable to the predicate devices.

1) Design Verification - Dimensional Analysis of the IZI Disposable Passive Accessory Probe. The System calculates and determines the position and angle of the probe based on the three dimensional location of the five passive reflective sphere markers that are mounted on the probe. Dimension accuracy and precision is an important technical characteristic that ensures the subject device is compatible with the StealthStation® System and that the subject device is comparable to the predicate device. A dimensional analysis of the Disposable Passive Accessory and the predicate device was performed to ensure the disposable part meets engineering specifications and the subject device is as precise and accurate as the predicate device. All critical dimensions that affect the passive reflective marker locations and the probe tip location

were measured in the Study against the predicate device. The CpK of all dimensions are greater than 1.0.

2) Design Verification - IZI Disposable Accessory with the Medtronic StealthStation S7
The Study was conducted to ensure the compatibility of the devices with the Medtronic StealthStation® system and confirming it is suitable for its intended use. The Study verified product performance in the StealthStation® patient registration process and measured navigation accuracy using a pre-scanned Medtronic IGS dummy head. Regarding patient registration and navigation error, the IZI Disposable Passive Accessory performs comparably to the Medtronic Planar Probe with manually mounted Spherz.

The two studies verify that the subject device is as safe and effective as the predicate device, and that the subject device is comparable to the predicate device.

VIII. CONCLUSION

The non-clinical data support the safety of the device and the hardware verification and validation demonstrate that the IZI Disposable Passive Accessory device should perform as intended in the specified use conditions. The non-clinical data demonstrate that the IZI Disposable Passive Accessory device performs comparably to the predicate device that is currently marketed for the same intended use.