August 7, 2019

IZI Medical Products LLC
% Mr. Daniel Ziskind
Director, Quality & Regulatory
7D Surgical Inc.
60 Scarsdale Road, Unit 118
Toronto, Ontario, M3B 2R7
Canada

Re: K191012
Trade/Device Name: Navigated Pedicle Access Kit
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 29, 2019
Received: July 30, 2019

Dear Mr. Ziskind:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K191012

Device Name
Navigated Pedicle Access Kit

Indications for Use *(Describe)*
The Navigated Pedicle Access Kit is intended to be used in image guided surgery with the 7D Surgical System. The Navigated Pedicle Access Kit is intended for use in posterior spinal surgery to assist in the accurate placement of pedicle screws. 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

IZI Navigated Pedicle Access Kit

This summary is submitted in accordance with 21CFR §807.92.

Submitter's name
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IZI MEDICAL PRODUCTS LLC
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Owings Mills, MD 21117

Date prepared: April 12, 2019

1. Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/usual name: Stereotaxic Instrument

Proprietary name: Navigated Pedicle Access Kit

These devices are classified as follows:

Classification Name	**21 CFR Section**	**Product Code**
Stereotaxic Instrument	21 CFR §882.4560	OLO

2. Predicate Devices

The IZI Pedicle Access Kit is substantially equivalent to the following currently marketed devices:

Product	**510(k)**
7D Surgical System	K180352 (Primary Predicate)

Reference Devices:

Product	**510(k)**
Medtronic HORIZON Spinal System	K182928
IZI Medical Disposable Passive Accessory	K142344

3. Indications for Use

The Navigated Pedicle Access Kit is intended to be used in image guided surgery with the 7D Surgical System. The Navigated Pedicle Access Kit is intended for use in posterior spinal surgery to assist in the accurate placement of pedicle screws. The device is sterile and designed for single use.

4. Device Description

The IZI Pedicle Access Kit consists of one pedicle access needle with cannula. The handle contains 4 retro-reflective Navigation Markers (Spherz K022074). The device is sterile and designed for single use. The patient-contacting components are the stainless-steel cannulas and needle. The product is used to gain access to the pedicle in image guided surgeries using the 7D Surgical System. The retro-reflective Navigation Markers (Spherz) that are attached to the handle allows the camera system of 7D Surgical System (K180352) to accurately locate where the tip of the needle is in space.

5. Comparison of Technological Characteristic with the Predicate Device

The IZI Navigated Pedicle Access Kit is substantially equivalent to the predicate device in terms of intended use, function, and overall performance.

Biocompatibility Profile – The IZI Pedicle Access Kit has the same biocompatibility profile as the reference device K1423244.

6. Nonclinical Performance Data

Verification and Validation activities have been conducted to provide assurance that the device meets the performance requirements under the indications for use conditions.

The following accuracy testing has been performed using the 7D Surgical System to ensure the substantial equivalence of the IZI Navigated Pedicle Access Kit device:

- Non-Clinical Performance Surgical Simulations Conducted on Phantom Models
- Compliance Conformity Assessments
    - ASTM F2554-10 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems

Device performance tests were performed to verify the absolute accuracy and repeatability of the accuracy of the device, and the navigation accuracy according to ASTM F2554-10. In addition, Target Registration Error (TRE) has been used to evaluate the clinical accuracy of the system on phantom models in a clinical simulated environment. TRE evaluates the error discrepancy between the position reported by the image guided surgery system and the ground truth position measured physically or otherwise.

7. Conclusion

The IZI Navigated Pedicle Access Kit is substantially equivalent to the predicate devices identified above:

- The predicate devices and IZI Navigated Pedicle Access Kit use equivalent technologies.
- The predicate devices and IZI Navigated Pedicle Access Kit are designed and manufactured to the similar physical safety standards.

The non-clinical verification and validation performed support the substantial equivalence of the IZI Navigated Pedicle Access Kit compatibility with the 7D Surgical System. The conclusions drawn from the non-clinical tests demonstrate that the IZI Navigated Pedicle Access Kit performs as safely and effectively as the legally marketed device according to the comparison based on the requirements of 21 CFR §882.4560 and the information provided herein. It is concluded that the IZI Navigated Pedicle Access Kit is substantially equivalent to the predicate device with respect to its indications for use, technological characteristics, and performance characteristics.