March 23, 2021

7D Surgical Inc.
Daniel Ziskind
Director, Quality & Regulatory
60 Scarsdale Road, Unit 118
Toronto, Ontario M3B 2R7
Canada

Re: K210555
Trade/Device Name: 7D Surgical System - Drill Guide
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 13, 2021
Received: February 25, 2021

Dear Daniel 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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210555

Device Name
7D Surgical System Drill Guide

Indications for Use *(Describe)*
The 7D Surgical System is a stereotaxic image guidance system intended for the spatial positioning and orientation of spinal surgical instruments used by surgeons. The system is also intended to be used as the primary surgical luminaire during image guided surgery. The device is indicated for posterior approach spine surgery where reference to a rigid anatomical structure can be identified.

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.

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510(k) Summary of Safety and Effectiveness

7D Surgical System

This summary of safety and effectiveness information is submitted in accordance with 21CFR §807.92.

1. **Submitter's name, address, telephone number, contact person.**

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Contact person: Daniel Ziskind
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Email: daniel.ziskind@7dsurgical.com

Date prepared: February 13, 2021

2. **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: Computer-assisted surgical device
Proprietary name: 7D Surgical System - Drill Guide

These devices are classified as follows:

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

3. **Substantially Equivalent Devices**

7D Surgical believes the 7D Surgical System Drill Guide is substantially equivalent to the following currently marketed devices:

Product	**510(k)**
7D Surgical System (Compatibility with the Medtronic Universal Drill Guide)	K180352

The indications for use of the subject device 7D Surgical System are equivalent to the predicate device K180352. Furthermore, the technological characteristics of the 7D

Surgical System are substantially equivalent. The differences in the technological characteristics do not raise new questions of safety and effectiveness. Consequently, the subject is substantially equivalent to the predicate device.

4. Purpose of Submission

7D Surgical intends to introduce the 7D Surgical Drill Guide which assists surgeons with positioning of a drill to create the canal for screw placement. Similar to the existing 7D Surgical tool sets, these stereotactic instruments are optically tracked by reflective marker spheres to locate the instruments' position and orientation relative to the patient's tomographic image. The 7D Surgical Drill Guide is exclusively used with the 7D Surgical System.

5. Indications for Use

The 7D Surgical System is a stereotaxic image guidance system intended for the spatial positioning and orientation of spinal surgical instruments used by surgeons. The system is also intended to be used as the primary surgical luminaire during image guided surgery. The device is indicated for posterior approach spine surgery where reference to a rigid anatomical structure can be identified.

6. Device Description and Technical Comparison to Predicate Devices

The 7D Surgical System is intended for use as a stereotaxic image guided surgical navigation system during spine surgery. The system provides image registration between preoperative scan data and data captured intraoperatively from the 7D Surgical System structured light scanner and/or user selected points. The system provides guidance data by tracking and displaying the position and orientation of wireless optically tracked Spinal Instruments including the 7D Surgical Pedicle Probe and Awl, now including the 7D Surgical Drill Guide, relative to the patient. Position and orientation data of tracked Spinal Instruments are linked to the preoperative scan data using the 7D Surgical System workstation. The system is intended to be used as the primary surgical luminaire for image guided surgery.

The 7D Drill Guide is designed to allow the 7D Spine Module to show real-time interaction of the drill guide with the patient. The 7D Drill Guide is used to extend the initial hole through the cancellous (soft) bone of the vertebra passing the pedicle. The 7D Drill Guide Instrument Set contains several inserts and bits, these can be switched during the procedure. During navigation, the 7D Drill Guide is displayed showing the trajectory of its path, including measurement markings for measuring the depth of the proposed insertion. These measurement markings can be used as a guide to select the appropriate length of the screw for instrumentation.

7. Safety Considerations

This change to add compatibility to the 7D System to include navigational tracking of the Drill Guide did not impact conformity to regulatory compliance standards as only the system software has been modified to support this new feature. Software, Mechanical Design, and User Instructions risk control measures have been implemented to ensure all new risks associated with use of the Drill Guide have been adequately controlled.

8. Technological Characteristics

The literature research and the comparison to the predicate devices show that the device makes use of equivalent technological characteristics and functionality and is intended for equivalent surgical procedures as compared to the predicate devices.

9. 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.

7D Surgical performed the following testing to ensure the safety and effectiveness of the 7D Surgical System device:

- Non-Clinical System, Software, and Instrumentation Verification and Validation
- 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) have been used to evaluate the clinical accuracy of the system on phantom models in a clinical simulated environment. TRE and ATE evaluates the error discrepancy between the position reported by the image guided surgery system and the ground truth position measured physically or otherwise.

The following table contains a summary of verification and validation performed on the 7D Surgical System:

Verification and Validation	Description	Conclusion
System Verification	Scope of the test is to verify the design requirement specifications of 7D Surgical System under test case protocols.	Verification successful, all design requirements have been fulfilled.
System Validation	Scope of the test is to validate the Indications For Use and Customer Requirements of the 7D Surgical System under	Validation successful, all user needs met.

Verification and Validation	Description	Conclusion
	simulated use case situations.	
Safety regarding risk analysis	Implementation and effectiveness of all risk control requirements specified in the 7D Surgical System risk analysis are tested and verified.	Risk Control requirements are effective and mitigate the associated risks to an acceptable level.
Non-Clinical Accuracy	System's accuracy is tested using the 7D Surgical System on phantom models following the ASTM F2554-10 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems in addition to Target Registration Error.	All accuracy specifications have been met for the Drill Guide.

All non-clinical tests successfully passed demonstrating that the subject device performs as safely and effectively as the predicate device and supporting substantial equivalence.

10. Clinical Data

A clinical trial was not required to demonstrate safety and effectiveness of the 7D Surgical System. Clinical validation is unnecessary as the 7D Surgical System introduces no new indications for use, and device features are equivalent to the previously cleared predicate device identified. The clinical safety and effectiveness of Image Guided Surgery Systems are historically accepted for both the predicate and subject device.

11. Conclusion

The 7D Surgical System is substantially equivalent in safety and effectiveness to the predicate devices identified above:

- The predicate devices and 7D Surgical System use equivalent technologies.
- The predicate devices and 7D Surgical System are designed and manufactured to the similar electrical and physical safety standards.

The non-clinical verification and validation performed support the safety and effectiveness of the 7D Surgical System Drill Guide. The conclusions drawn from the non-clinical tests demonstrate that the 7D Surgical System 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 7D Surgical System Drill Guide is substantially equivalent to the predicate device with respect to its indications for use, technological characteristics, and performance characteristics.