May 20, 2022

7D Surgical
Daniel Ziskind
Director, Quality & Regulatory
60 scarsdale road, unit 118
Toronto, Ontario M3B 2R7
Canada

Re: K220522
Trade/Device Name: 7D Surgical System - Percutaneous Application (7D Flash Frame)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 20, 2022
Received: April 20, 2022

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)*
K220522

Device Name
7D Surgical System - Percutaneous Application (7D Flash Frame)

Indications for Use *(Describe)*
The 7D Surgical System Percutaneous Application 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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K220522

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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60 Scarsdale Road, Unit 118
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Contact person: Daniel Ziskind
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7D Surgical ULC
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Email: daniel.ziskind@7dsurgical.com

Date prepared: February 22, 2022

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 - Percutaneous Application (7D Flash Frame)

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 and Percutaneous Application is substantially equivalent to the following currently marketed devices:

Product	**510(k)**
7D Surgical Percutaneous Application (7d Registration Frame, 7d Flex Iliac Pin Connector, 7d Pin Guide Block, 7d 3.2 Mm Steinmann Pin, 7d Iliac Crest Pin Chuck & Key)	K210457 - Primary Predicate

The indications for use of the subject device 7D Surgical System are equivalent to the predicate device K210457. 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

The proposed change for the 7D Surgical System is to introduce the 7D Surgical Flash Frame for the previously cleared Percutaneous Application (K210457) which provides minimally invasive image guided spine surgery. Similar to the previous 7D Surgical System K210457, the device registers tomographic DICOM data to structured light images which utilizes intra-operative tomographic scans.

The proposed application intends to introduce the Sterile, Single Use Flash Frame which is applied above the patient skin over the patient drape, similar to the currently cleared 7D Registration Frame, in the region of interest where registration is intended. The major change from the previous Registration Frame is that the proposed Flash Frame has no marker posts to attach optical marker spheres which track the position of the frame in relation to patient Reference Frame during structured light acquisition. In addition, the Flash Frame is provided sterile as opposed to the previous non-sterile Registration Frame.

5. Indications for Use

The 7D Surgical System Percutaneous Application 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 minimally invasive spine surgery. The system performs Percutaneous image guided surgery by acquiring an intra-operative tomographic scan of the patient with the 7D Surgical Flash Frame attached to the patient's skin over the incision drape in the region of interest where the spine surgery is to be performed. In addition, the intra-operative tomographic scan is taken with the 7D Surgical Reference Frame rigidly attached to either the spine or iliac crest. The 7D System then generates a three-dimensional (3D) image of the surgical site and the 7D Flash Frame. Registration is performed by the system software registering points from the 7D Flash Frame generated from the 3D intra-operative tomographic scan to the 3D structured light image generated by the system.

The major difference between the previous spine application and the proposed Percutaneous Application is that registration is now performed using the sterile single use Flash Frame. Similar to the previous Registration Frame, registration is performed by picking landmarks on the frame which is placed on the patient drape above the patient skin. Verification of the registration must be confirmed by using a tracked navigational tool on the boney anatomy of the spine prior to navigation. It should be noted that there have been no changes to the previous 7D Surgical System hardware and Percutaneous tool sets with exception to the introduction of the Flash Frame and the Percutaneous Application to enable use of this new instrument.

7. Safety Considerations

This change to add compatibility to the 7D System to include navigational tracking of the Percutaneous Application 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 Percutaneous Application 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 demonstrate equivalence to the predicate device:

- Non-Clinical System, Software, and Instrumentation Verification and Validation
- Non-Clinical Performance Surgical Simulations Conducted on Phantom Models
- Compliance Conformity Assessments
- Sterilization and Packaging Validation Studies for 7D Surgical Flash Frame

Device performance tests were performed to verify the absolute accuracy and repeatability of the accuracy of the device, and the navigation accuracy. Target Registration Error (TRE)

has been used to evaluate the simulated accuracy of the system on phantom models in a 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.

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 simulated use case situations.	Validation successful, all user needs met.
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 using Target Registration Error.	All accuracy specifications have been met for the Percutaneous Application.

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.

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 demonstrate that the 7D Surgical System Percutaneous Application meets design specifications. The conclusions drawn

from the non-clinical tests demonstrate that the 7D Surgical System performs as safely and effectively as the legally marketed predicate 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 is substantially equivalent to the predicate device with respect to its indications for use, technological characteristics, and performance characteristics.