September 3, 2020

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

Re: K201966
Trade/Device Name: 7D Surgical FlashLock 1, 7D Surgical Flex Rod Connector - 5.5 mm - 150 mm, 7D Surgical Flex Array
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 13, 2020
Received: July 15, 2020

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)*
K201966

Device Name
7D Surgical FlashLock 1, 7D Surgical Flex Rod Connector - 5.5 mm - 150 mm, 7D Surgical Flex Array

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

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
Toronto, ON, M3B 2R7, Canada

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

Date prepared: July 06, 2020

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 FlashLock 1, 7D Surgical Flex Rod Connector - 5.5 mm - 150 mm, 7D Surgical Flex Array

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 FlashLock and Flex Rod is substantially equivalent to the following currently marketed devices:

Product	**510(k)**
7D Surgical System	K180352(primary) and K192140(secondary)

The indications for use of the subject device 7D Surgical System are equivalent to the predicate device K180352 and K192140. 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 FlashLock and Flex Rod instruments.

The 7D Surgical Flex Rod used in conjunction with the 7D Surgical Flex Array is intended to be used as a patient referencing device when attached to a pedicle screw which has been inserted into the vertebral body. It should be noted that the Flex Array has identical tracking marker sphere configuration as the currently marketed 7D Surgical Reference Clamp. The Flex Array and Flex Rod assembly is identical in intended use to the current Reference Clamp except in the way it is rigidly attached to the spine. The currently marketed 7D Surgical patient referencing device is rigidly attached to the spine by use of an Ikuta Clamp design, whereas the Flex Rod attaches to an already implanted pedicle screw.

The 7D Surgical FlashLock is a ¼" quick connect adapter that has a rotatable tracking marker sphere array. The FlashLock requires a non-tracked insert and handle to be attached to it. Examples of inserts that can be used are drill bits, taps, and screwdrivers that have a ¼" quick connect interface. Examples of handles are T-handles, ratcheting handles or surgical drills. Once calibrated using the 7D Surgical calibration device, the user can rotate the handle and insert while holding the FlashLock array stationary facing the 7D Surgical System tracking camera.

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 FlashLock and Flex Rod, 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. Similar to the previously cleared 7D

Surgical System, the system tracks the position and orientation of a FlashLock and Flex Rod.

The system is intended to be used for both image fusion and navigation for neurological applications where reference to a rigid structure can be identified relative to a preoperative image data of the anatomy.

The **Tracking System** enables the surgeon to view the position and orientation of 7D Surgical System Spinal Instruments relative to registered preoperative image data while performing the surgical procedure. Each of the 7D Surgical System instruments, including the FlashLock and Flex Rod, utilizes commercially available passive reflective marker spheres to determine the position and orientation of instruments. Each tracked Instruments requires a unique marker position configuration to enable the tracking system to distinguish the tools from one to the other.

The **Software** links all system components and displays navigational data to the surgeon. It provides methods for loading preoperative scans and guides the surgeon through the process of surface model creation, structured light acquisition, registration, registration verification, and navigation.

7. Safety Considerations

This change to add compatibility to the 7D System to include navigational tracking of the FlashLock and Flex Rod 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 FlashLock and Flex Rod 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) and Angular Trajectory Error (ATE) has 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 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.
Product Safety standards	The 7D Surgical System and Instrumentation was tested to the following recognized standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-41, IEC 60825-1, ISO 10993-1, and ISO 17665-1.	Compliance with recognized standards have been verified in the previous application. Previous test results have not been affected by this change.
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 FlashLock and Flex Rod.

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 compatibility with the FlashLock and Flex Rod. 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 is substantially equivalent to the predicate device with respect to its indications for use, technological characteristics, and performance characteristics.