November 27, 2019

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

Re: K192945
Trade/Device Name: 7D Surgical System Cranial Biopsy and Ventricular Catheter Placement Application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: October 15, 2019
Received: October 30, 2019

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,

For Matthew Krueger
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K192945

Device Name

7D Surgical System Cranial Biopsy and Ventricular Catheter Placement Application

Indications for Use *(Describe)*

The 7D Surgical System is a stereotaxic image guidance system intended for the spatial positioning and orientation of neurosurgical 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 cranial 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 Cranial Application

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

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

7D Surgical, Inc.
60 Scarsdale Road, Unit 118
Toronto, ON, M3B 2R7, Canada

Contact person: Daniel Ziskind
Quality and Regulatory, Director
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Email: daniel.ziskind@7dsurgical.com

Date prepared: November 18, 2019

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 Cranial Biopsy and Ventricular Catheter Placement Application

These devices are classified as follows:

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

3. **Substantially Equivalent Devices**

7D Surgical believes the 7D Surgical System Cranial Biopsy and Ventricular Catheter Placement Application is substantially equivalent to the following currently marketed devices:

Product	**510(k)**
7D Surgical System Cranial Application	K181041

The indications for use of the subject device 7D Surgical System Cranial Biopsy and Ventricular Catheter Placement Application are equivalent to the predicate device 7D Surgical System Cranial Application K181041. Furthermore, the technological characteristics of the 7D Surgical System Cranial Application 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. It is important to note the 7D Surgical System Cranial Application K181041 is considered the Primary Predicate Device for this application.

4. Purpose of Submission

The purpose of this submission is intended introduce the 7D Surgical Cranial Biopsy and Ventricular Catheter Placement Application. With the 7D Surgical Biopsy Guide surgeons can target lesions with pre-planned trajectories and provide real-time tracking of the IZI Navigable Brain Biopsy Cannula K143241. The Biopsy Guide offers continuous position feedback and precise step-by-step workflow guidance for a variety of procedures. Surgeons are able to take biopsies and place Ventricular Catheters in the cranium through passive-marker technology. The articulating arm design connects directly to the skull head clamp for accurate positioning and the best approaches for the IZI Biopsy Needle and Ventricular Catheters.

The IZI Navigable Brain Biopsy Cannula K143241 is designed for navigated removal of tissue samples in frameless neurosurgery procedures. The 7D Surgical System stores the pre-calibrated geometry of the IZI Navigable Brain Biopsy Cannula allowing for instant use for navigation. Together with 7D Surgical Biopsy Guide and the 7D Surgical System Cranial Navigation application, pre-planned trajectories can be quickly targeted.

5. Indications for Use

The 7D Surgical System is a stereotaxic image guidance system intended for the spatial positioning and orientation of neurosurgical 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 cranial surgery where reference to a rigid anatomical structure can be identified.

6. Device Description and Technical Comparison to Predicate Devices

The 7D Surgical System Cranial Biopsy and Ventricular Catheter Placement Application is intended for use as a stereotaxic image guided surgical navigation system during cranial surgical procedures. The Cranial Application software assists in guiding surgeons during cranial surgical procedures such as biopsies, tumor resections, and Ventricular Catheters placement. The Cranial Application software works in conjunction with 7D Surgical Machine Vision Guidance System which consists of clinical software, optically tracked surgical Pointer, a reference frame

instrument and platform/computer hardware which is substantially equivalent to K181041. Image guidance tracks the position of instruments in relation to the surgical anatomy and identifies this position on DICOM images or intraoperative structured light images of the patient. The Cranial software functionality is described in terms of its feature sets which are categorized as imaging, registration, planning, and views. Feature sets include functionality that contributes to clinical decision making and are necessary to achieve system performance.

It is important to note that the fundamental technology of the Cranial Application is equivalent to the currently cleared Spinal and Cranial Application. Both applications require structured light imaging provided by the currently marketed system cart hardware. The system provides image registration between preoperative scan data and data captured intraoperatively from the 7D Surgical System integrated structured light scanner and/or user selected points of the Cranium. The system provides guidance data by displaying the locations of wireless optically tracked 7D Surgical System Cranial Instruments (examples include Reference Frame, Pointer, and now the Biopsy Guide) relative to the patient. Position and orientation data of tracked 7D Surgical System Cranial 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 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 pre-operative image data of the anatomy.

The 7D Surgical System Cranial Application is comprised of 5 major components:

1. Cart
2. Arm
3. Head
4. Tracked 7D Surgical System Cranial Instruments
5. Software

The **Cart** of the system serves the following purposes:

- Easy movement of system with secure attachment of all moveable components to the cart
- Space efficient storage of system, when not used
- Allow stable positioning of the entire system when in use
- Safe enclosure of the computer and electric supplies
- Allow user interaction and data-transfer to and from the computer workstation

The **Arm** of the system serves the following purposes:

- Link the cart and the head allowing easy positioning of the head by the sterile surgeon but is stable otherwise (no motion of the head after positioning)
- Allow positioning of the head outside of the sterile field in all positions
- Provides mechanisms for routing cables between the head and the cart

The **Head** of the system serves 3 main purposes:

- Capture 3D structured light images of the intraoperative patient anatomy to facilitate registration of patient preoperative data with the local surgical coordinate system to enable surgical navigation
- To passively track the location of 7D Surgical System Cranial Instruments - Pointer and a Reference Frame within the surgical field and provide intraoperative guidance to the surgeon.
- To illuminate the surgical field during navigated portions of the surgery. The incorporation of an illumination module into the system is driven by the fact that external surgical lighting can prevent the acquisition of structured light images due to saturation of cameras during registration.

The **Tracking System** enables the surgeon to view the position and orientation of these 7D Surgical System Cranial Instruments relative to registered pre-operative image data while performing the surgical procedure. Each 7D Surgical System Instrument utilizes 4 commercially available passive reflective marker spheres used to determine the position and orientation of each 7D Surgical System Instrument. Each 7D Surgical System Instrument 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. 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.

8. 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
    - ISO 10993-1 Biological evaluation of medical devices.
    - ISO 17665-1 Sterilization of health care products – Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
    - AAMI / ANSI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013, (Consolidated Text) Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities. (Sterility)

Device performance tests were performed to verify the absolute accuracy of the accuracy of the device. 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 tables summarizes the results of Target Registration Error (TRE) and Trajectory Angle Error of the 7D Surgical System Cranial Biopsy Guide Application:

	Mean	**Standard Deviation**	**99% CI[*)] Upper Limit**
Target Registration Error (TRE) [mm]	1.36	0.68	1.44
Trajectory Angle Error [°]	1.35	0.74	1.43

The following table contains an overall summary of verification and validation performed on the 7D Surgical System Cranial Application:

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.
Usability	This test is conducted to validate the 7D Surgical System with respect to use errors.	Validation successful, device safe and effective with respect to use errors.
Safety regarding risk analysis	Implementation and effectiveness of all risk control requirements specified in the 7D Surgical System risk analysis is tested and verified.	Risk Control requirements are effective and mitigate the associated risks to an acceptable level.
Biocompatibility	The 7D Surgical System Cranial Instrumentation was assessed to the following recognized standards: ISO 10993-1	Compliance with recognized standards has previously been established in the predicate device.
Sterilization	The 7D Surgical System Cranial Instrumentation was tested to the following recognized standards: ISO 17665-1.	Compliance with recognized standards have been verified in this application.
Product Safety standards	The 7D Surgical System was tested to the following recognized standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-41, and IEC 60825-1.	Compliance with recognized standards have been verified.
Non-Clinical Accuracy	System's accuracy is tested using the 7D Surgical System on phantom models to determine Target Registration Error and Angular Trajectory Error	All accuracy specifications have been met.

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

It is important to note that the following Compliance Conformity Assessments were not required as a result of design implementation of the Cranial Application, as no substantial changes were made to the system cart. The information provided in application K181041 is still applies to the current 7D Surgical System:

- IEC 60601-1 Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2007
- IEC 60601-2-41 Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
- IEC 60601-1-6 Medical Electrical Equipment - Part 1-6, General Requirements for Basic Safety and Essential Performance - Usability
- IEC 60825-1 Safety of laser products - Part 1: Equipment classification and requirements

9. Clinical Data

A clinical trial was not required to demonstrate safety and effectiveness of the 7D Surgical System Cranial Biopsy and Ventricular Catheter Placement Application. Clinical validation is unnecessary as the 7D Surgical System Cranial Biopsy and Ventricular Catheter Placement Application 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.

10. Conclusion

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

- The predicate devices and 7D Surgical System use essentially the same technologies.
- The predicate devices and 7D Surgical System instrumentation have essentially the same materials and performance requirements.
- The predicate devices and 7D Surgical System are designed and manufactured to similar electrical and physical safety standards.

The non-clinical verification and validation performed support the safety and effectiveness of 7D Surgical System C Cranial Biopsy and Ventricular Catheter Placement Application. The conclusions drawn from the nonclinical 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.