DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

December 29, 2016

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

Re: K162375
Trade/Device Name: Envision 3D™: Image Guidance System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 29, 2016
Received: November 30, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Caroline Rhim -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K162375

Device Name
Envision 3D™: Image Guidance System

Indications for Use *(Describe)*

The Envision 3D™: Image Guidance 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 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

Envision 3D™: Image Guidance 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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Email: daniel.ziskind@7dsurgical.com

Date prepared: August 23, 2016

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: Envision 3D™: Image Guidance System

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 Envision 3D™: Image Guidance System is substantially equivalent to the following currently marketed devices:

Product	**510(k)**
Medtronic StealthStation System	K133444

The indications for use of the subject device Envision 3D™: Image Guidance System are equivalent to the predicate device K133444. Furthermore, the technological characteristics of the Envision 3D™: Image Guidance 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. Device Description and Technical Comparison to Predicate Devices

The 7D Surgical Envision 3D™: Image Guidance 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 Envision 3D™ integrated structured light scanner and/or user selected points. The system provides guidance data by displaying the locations of wireless optically tracked Envision 3D™ Spinal Instruments (examples include pedicle probe and awl) relative to the patient. Position and orientation data of tracked Envision 3D™ Spinal Instruments are linked to the preoperative scan data using the Envision 3D™ 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 Envision 3D™: Image Guidance System is comprised of 5 major components:

1. Cart
2. Arm
3. Head
4. Tracked surgical Envision 3D™ Spinal 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 Envision 3D™ Spinal Instruments - awl, pedicle probe) 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 the use of standard surgical lighting during navigated parts of the procedure prevent the acquisition of structured light images due to saturation of cameras.

The **Tracking System** enables the surgeon to view the position and orientation of these Envision 3D™ Spinal Instruments relative to registered pre-operative image data while performing the surgical procedure. Each Envision 3D™ Instrument utilizes 4 commercially available passive reflective marker spheres [Manufactured by NORTHERN DIGITAL, INC.; 510(k) K033621] used to determine the position and orientation of each Envision 3D™ Instrument. Each Envision 3D™ 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.

5. Indications for Use

The Envision 3D™: Image Guidance 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 posterior approach spine surgery where reference to a rigid anatomical structure can be identified.

6. Safety Considerations

Electrical safety and EMC testing were conducted on Envision 3D™: Image Guidance System. The device complies with recognized electrical safety standards: IEC 60601-1

standard for electrical safety and IEC 60601-1-2 standard for electromagnetic compatibility.

The biocompatibility evaluation Envision 3D™: Image Guidance System instrumentation has been conducted in accordance with ISO 10993 standards and blue book memorandum #G95-1 entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing", May 1, 1995. The evaluation reveals that biocompatibility requirements are met.

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 Envision 3D™ device:

- Non-Clinical System, Software, and Instrumentation Verification and Validation
- Non-Clinical Performance Surgical Simulations Conducted on Phantom Models
- Surgeon Performed Human Cadaveric Workflow Study
- Cadaveric Porcine Study Performed on Reference Frame Clamp Stability
- Compliance Conformity Assessments
    - 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
    - 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)
- 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 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.

The following table contains a summary of verification and validation performed on the Envision 3D™: Image Guidance System

Verification and Validation	Description	Conclusion
System Verification	Scope of the test is to verify the design requirement specifications of Envision 3D™ 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 Envision 3D™ System under simulated use case situations.	Validation successful, all user needs met
Usability	This test is conducted to validate the Envision 3D™ System with respect to use errors.	Validation successful with respect to use errors
Safety regarding risk analysis	Implementation and effectiveness of all risk control requirements specified in the Envision 3D™ risk analysis are tested and verified.	Risk Control requirements are effective and mitigate the associated risks to an acceptable level.
Product Safety standards	The Envision 3D™ 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

Verification and Validation	Description	Conclusion
Non Clinical Accuracy	System's accuracy is tested using the Envision 3D™ 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

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

9. Clinical Data

A clinical trial was not required to demonstrate safety and effectiveness of the Envision 3D™: Image Guidance System. Clinical validation is unnecessary as the Envision 3D™: Image Guidance System introduces no new indications for use, 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 Envision 3D™: Image Guidance System is substantially equivalent in safety and effectiveness to the predicate devices identified above:

- The predicate devices and Envision 3D™ use essentially the same technologies
- The predicate devices and Envision 3D™ 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 Envision 3D™: Image Guidance System. The conclusions drawn from the nonclinical tests demonstrate that the Envision 3D™ 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 Envision 3D™ System is substantially equivalent to the predicate device with respect to its indications for use, technological characteristics and performance characteristics.