January 17, 2020

Osseus Fusion Systems
% J. D. Webb
Official Correspondent
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven, Utah 84401

Re: K192495
Trade/Device Name: Black Diamond Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 5, 2019
Received: September 11, 2019

Dear J. Webb:

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)*
K192495

Device Name
Black Diamond Navigation Instruments

Indications for Use *(Describe)*
The Black Diamond Navigation Instruments are intended to be used during the preparation and placement of Black Diamond pedicle screws during spinal surgery to aid the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Black Diamond Navigation Instruments are specifically designed for use with the Medtronic Stealth Station System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

*5*10(k) Summary: Black Diamond Navigation Instruments

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	January 9, 2020
Submitted By	Osseus Fusion Systems, LLC 2703 W. Mockingbird Ln., Ste. #102 Dallas, TX 75204
Primary Contact	J.D. Webb 4313 W. 3800 S West Haven, UT 84401 512-590-5810 Tele e-mail: jdwebb@orthomedix.net
Trade Name	Black Diamond Navigation Instruments
Common Name	Orthopedic Stereotaxic instrument
Classification Name	Stereotaxic Instrument
Class	II
Product Code	OLO
CFR Section	21 CFR section 882.4560
Device Panel	Orthopedic
Primary Predicate Device	Navigated CD Horizon Solera Screwdrivers and Taps, Medtronic Sofamor Danek, USA Inc. (K140454)
Secondary Predicate Devices	Universal Navigation Instruments for EXPEDIUM® and VIPER® MIS Spine Systems, DePuy Spine, Inc (K140927) SeaSpine Navigation System, SeaSpine Orthopedics Corporation (K172517)
Reference Predicate Devices	Black Diamond Pedicle Screw System, Osseus Fusion Systems (K131810)
Device Description	Black Diamond Navigation Instruments are non-sterile, reusable instruments; including probes, bone taps, and inserters that are operated manually. These instruments are intended to be used within the context and limitations of the indications for use for Osseus Fusion System's FDA-cleared Black Diamond system and the Medtronic Synergy Experience StealthStation System S7 (v2.1.0). Use of these navigation systems provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement.
Materials	Stainless steel per ASTM F899
Substantial Equivalence Claimed to Predicate Devices	The Black Diamond Navigation Instruments are substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

Indications for Use	The Black Diamond Navigation Instruments are intended to be used during the preparation and placement of Black Diamond pedicle screws during spinal surgery to aid the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Black Diamond Navigation Instruments are specifically designed for use with the Medtronic Stealth Station System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.
Summary of the technological characteristics compared to predicate	When compared to the predicate devices, Black Diamond Navigation Instruments have the same intended use and similar technological characteristics, including: • Design • Materials of Construction • Function/Performance • Fundamental Scientific Technology • Principle of Operation
Non-clinical Test Summary	Nonclinical testing was performed to show that the subject Black Diamond Navigation Instruments are substantially equivalent to the predicate device. The following testing was performed: • Accuracy testing • Compatibility testing • Performance testing The results of these evaluations indicate that the Black Diamond Navigation Instruments are equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Osseus Fusion Systems considers the Navigation Instruments to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials, and indications for use.