November 3, 2022

Osseus Fusion Systems
% Daniel Johnson
Regulatory Engineer
Jalex Medical LLC
27865 Clemens Rd
Suite 3
Westlake, Ohio 44145

Re: K222107
Trade/Device Name: Black Diamond™ POCT Spinal System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG
Dated: August 5, 2022
Received: August 8, 2022

Dear Daniel Johnson:

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,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222107

Device Name
Black Diamond™ POCT Spinal System

Indications for Use *(Describe)*
The Black Diamond™ POCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (Cl to C7) and the upper thoracic spine (Tl-T3); traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusion (e.g., pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin, as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Black Diamond™ POCT Spinal System is also intended to restore the integrity of the spinal column even in the absences of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. To achieve additional levels of fixation, the Black Diamond™ POCT Spinal System may be connected to the Osseus Black Diamond™ Pedicle Screw System using transition rods or anatomically-bent rods.

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.

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OSSEUS™

510(k) Summary

Submitted By: Osseus Fusion Systems
1931 Greenville Ave.
Suite 200
Dallas, TX 75206

Date: 07/15/22

Contact Person: Daniel Johnson, Regulatory Engineer
Contact Telephone: (440) 541-0060
Contact Fax: (440) 933-7839

Device Trade Name: Black Diamond™ POCT Spinal System
Device Classification Name: Posterior Cervical Screw System
Device Classification: Class II
Classification Regulation: 21 CFR 888.3075
Reviewing Panel: Orthopedic
Product Code: NKG
Predicate Device: K172495 – Precision Spine Reform POCT System
Reference Predicate: K131810/K192121 – Osseus Black Diamond™ Pedicle Screw System

Additional Predicates: K190071- Spineart Perla Posterior Cervico-Thoracic Fixation System
K171444 – K2M Yukon OCT Spinal System
The predicate devices have not been subject to any design related recalls.

Device Description:
The Black Diamond™ POCT Spinal System is a posterior cervico-thoracic fixation system intended to provide stabilization to promote fusion of the cervical spine and upper thoracic spine. The Black Diamond™ system contains rods in multiple shapes and sizes, polyaxial screws, set screws, rod connectors and transverse connectors. Connecting components can be locked to the rod in various configurations to accommodate individual patient anatomy.

Indications for Use Statement:
The Black Diamond™ POCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the upper thoracic spine (T1-T3); traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusion (e.g., pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin, as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Black Diamond™ POCT Spinal System is also intended to restore the integrity

of the spinal column even in the absences of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. To achieve additional levels of fixation, the Black Diamond™ POCT Spinal System may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.5mm to 5.5mm using transition rods or anatomically-bent rods.

Summary of Technological Characteristics:

The Black Diamond™ POCT Spinal System was found to be substantially equivalent to the predicate devices in terms of device description, intended use, implant materials, mechanical testing, biocompatibility and other technological characteristics including size offerings.

Non-clinical Testing:

Mechanical testing was performed on the Black Diamond System in static compression, dynamic compression, and static torsion per ASTM F1717.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.