April 2, 2025

SeaSpine Orthopedics Corporation
Cindy Toyama
Senior Regulatory Affairs Specialist
5770 Armada Drive
Carlsbad, California 92008

Re: K243659
Trade/Device Name: FLASH™ Facet Fusion Instruments IsoTis® Facet Fusion Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 26, 2024
Received: November 27, 2024

Dear Cindy Toyama:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243659

Device Name

FLASH™ Facet Fusion Instruments
IsoTis® Facet Fusion Instruments

Indications for Use *(Describe)*

The FLASH™ Facet Fusion Instruments are intended to be used during spinal surgery to assist the surgeon in precisely locating and preparing anatomical structures, specifically the lumbar facet joints, in either open or minimally invasive procedures. The FLASH™ Facet Fusion Instruments are specifically designed for use with the 7D Surgical 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 can be identified.

The IsoTis® Facet Fusion Instruments are intended to be used during spinal surgery to assist the surgeon in precisely locating and preparing anatomical structures, specifically the lumbar facet joints, in either open or minimally invasive procedures. The IsoTis® Facet Fusion Instruments are specifically designed for use with the 7D Surgical 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 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.

510(k) Summary

K243659

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation
Address: 5770 Armada Drive, Carlsbad CA
Phone number: 949.855.7175
Email: cindy.toyama@seaspine.com
Contact Person: Cindy Toyama, Senior Regulatory Affairs Specialist

Date prepared: April 2, 2025

Device Name

Device/Trade Names: FLASH™ Facet Fusion Instruments, IsoTis® Facet Fusion Instruments
Common Name: Orthopedic Stereotaxic Instrument
Classification Name: Stereotaxic Instrument (21 CFR §882.4560)
Class: II
Product Code: OLO

Legally Marketed Predicate Devices

510(k) Number	Product Code(s)	Trade Name(s)	Manufacturer
Primary Predicate Device			
K222753	OLO	SeaSpine 7D Navigation Instruments	SeaSpine Orthopedics Corporation
Additional Device(s)			
K240625	OLO	CORUS™ Navigation Access System	Providence Medical Technology, Inc.
K192140	OLO, HAW	7D Surgical System - Universal Tracking Clamp	7D Surgical ULC

Device Description

The FLASH™ Facet Fusion Instruments are a manually operated disposable instrument set to be used with the 7D Surgical System to assist the surgeon in precise site preparation during open or minimally invasive spinal surgery. The FLASH™ Facet Fusion Instruments consist of a Lumbar Inserter, a Navigation T-Handle, an Array Adaptor, a Lumbar Tamp and Lumbar Facet Drill. The product is provided sterile in a ready-to-use, single patient use container. The subject instruments are made of a combination of stainless steel and medical grade plastics commonly used in orthopedic procedures. The surgical instruments are intended for use as an adjunct to established posterior lumbar fixation procedures, where the Instrumentation enables the location and preparation of a facet joint defect with or without the use of Navigation and delivery of bone graft into the defect.

Indications for Use

The FLASH™ Facet Fusion Instruments are intended to be used during spinal surgery to assist the surgeon in precisely locating and preparing anatomical structures, specifically the lumbar facet joint, in either open or minimally invasive procedures. The FLASH™ Facet Fusion Instruments are specifically designed for use with the 7D Surgical 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 can be identified.

Comparison of Technical Characteristics to Predicate Devices

The FLASH™ Facet Fusion Instruments are intended for use as an adjunct to established posterior lumbar fixation spine procedures, where the Instrumentation enables the location and preparation of the facet joint, and delivery of bone graft into the joint. Similar to the predicate device, the subject instruments are specifically designed for use with the 7D Surgical System. The subject instruments have similar designs, principle of operation, fundamental scientific technology, materials, intended use, as the primary predicate device and incorporate similar design features to enable compatibility with the 7D Surgical System. Additionally, the subject instruments have similar designs and fundamental scientific technology as the reference predicate.

As with primary predicate device, the subject instruments are assembled and secured to a 7D Universal Array to allow activation with the 7D Surgical System and are then used by the surgeon to perform image-guided surgery. Unlike the primary predicate, the subject instruments are used to prepare the facet joints similar to the reference predicate. The minor differences do not raise any new issues of safety and effectiveness since the principal technology remains the same, and bench performance testing and human factors validation demonstrated that the modified subject device is safe and effective as the predicate device.

Summary of Non-Clinical Testing to Support Substantial Equivalence

SeaSpine performed the following testing to ensure safety and effectiveness:

- Non-Clinical Bench Performance Testing Bench testing was conducted to verify that the design outputs meet the design inputs. The functionality of the new or modified features was tested to ensure that system requirements and user needs were met as defined. Specifically, the navigation compatibility of the subject tool with the 7D Surgical System and facet decortication capability were verified and validated through testing. The results show that the subject device is substantially equivalent to the cleared predicates.
- Sterilization and Packaging Validation Studies
- Compliance Conformity Assessments
  - ISO 10993-1, Biological evaluation of medical devices.
  - ISO 11607-1, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems
  - ISO 11607-2, Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes

- ISO 11137-1, Sterilization of health care products - Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2, Sterilization of health care products - Radiation — Part 2: Establishing the sterilization dose.
- ISO 11137-3, Sterilization of health care products - Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control
- IEC 62366-1, Medical devices — Part 1: Application of usability engineering to medical devices
- ANSI/AAMI HE75, Human factors engineering — Design of medical devices
- ASTM F2554-22, Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems
- ISO 14971, Medical devices — Application of risk management to medical devices

Clinical Testing

A clinical trial was not required to demonstrate the safety and effectiveness of FLASH™ Facet Fusion Instruments. Clinical validation is unnecessary as FLASH™ Facet Fusion Instruments does not introduce new indications for use, and device features are substantially 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.

Conclusions

The submitted data demonstrate that the subject device, FLASH™ Facet Fusion Instruments, is substantially equivalent to the cited legally marketed predicate, SeaSpine 7D Navigation Instruments (K222753). The FLASH™ Facet Fusion Instruments have similar intended use and indications for use, similar technological characteristics, and similar principles of operation as the predicate. The minor technological differences between the FLASH™ Facet Fusion Instruments and its predicate device, raise no new issues of safety or effectiveness. The non-clinical performance data demonstrate that the FLASH™ Facet Fusion Instruments perform as expected and in a manner that is substantially equivalent to its predicate devices. Thus, the FLASH™ Facet Fusion Instruments are substantially equivalent.