February 26, 2026

Osteonic Co., Ltd.
Jisun Lee
Official Correspondent
405ho,505-2ho,505-3ho,508ho,603ho,902ho,1004ho,1005ho,1103ho
12f, 38, Digital-Ro 29-Gil, Guro-Gu 102ho, 103ho,105ho, 24
Seoul, 08381
Republic Of Korea

Re: K254182
Trade/Device Name: Aster
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 19, 2025
Received: December 23, 2025

Dear Jisun Lee:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

MAZIAR SHAH-MOHAMMADI -S

For: Colin O'Neill, M.B.E.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254182

Please provide the device trade name(s).

ASTER

Please provide your Indications for Use below.

The ASTER is intended for anterior cervical fixation (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:

510(k) Summary

Prepared on: 2026-01-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	OSTEONIC CO., LTD.
Applicant Address	405Ho,505-2Ho,505-3Ho,508Ho,603Ho,902Ho,1004Ho,1005Ho,1103Ho, 12F, 38, Digital-ro 29-gil, Guro-gu 102Ho, 103Ho,105Ho, 24, Digital-ro 27-gil, Guro-gu, 1012Ho, 1013Ho, 272, Digital-ro, Guro-gu Seoul 08381 Korea, Republic of
Applicant Contact Telephone	+82-2-6902-8411
Applicant Contact	Mrs. Jisun Lee
Applicant Contact Email	jisun@osteonic.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ASTER
Common Name	Spinal intervertebral body fixation orthosis
Classification Name	Appliance, Fixation, Spinal Intervertebral Body
Regulation Number	888.3060
Product Code(s)	KWQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K212139	Admiral ACP System	KWQ
K230546	SIGNEX	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The ASTER is an anterior cervical plate system made from titanium alloy in accordance with ASTM F136.
The system consists of various plates and screws, and fixation is achieved by inserting bone screws through the plate openings into the cervical vertebral bodies. Each plate includes locking caps designed to prevent screw back-out, and the locking caps are provided pre-assembled to the plate.
A variety of plate lengths and screw configurations are available to accommodate patient anatomy.
The product is supplied only in a non-sterile condition, and must be steam sterilized prior to use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ASTER is intended for anterior cervical fixation (C2-T1) for the following indications:
degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

Based on a comparison with the predicate devices, we conclude that the subject device shares the same intended use and technological characteristics.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The subject device (ASTER Anterior Cervical Plate System) is an anterior cervical plating system used with bone screws to provide anterior fixation for cervical fusion procedures. Non-clinical performance testing was conducted to support a determination of substantial equivalence to the predicate device.

Mechanical performance testing was performed using FDA-recognized consensus standards applicable to spinal plate systems, including:

ASTM F1717 (Static compression bending; Static torsion; Dynamic compression bending fatigue)

The bench testing results met the applicable acceptance criteria and demonstrated that the subject device provides mechanical performance comparable to the predicate device for its intended use.

Clinical data were not required to support a determination of substantial equivalence for the subject device.

Based on the non-clinical performance testing and comparison to the predicate device, the subject device has demonstrated that it is as safe, as effective, and performs as well as the legally marketed predicate device for the intended use. Therefore, substantial equivalence has been demonstrated.