May 12, 2026

Osteomni, Inc.
Gulten Shurdom
Director
9956 NW 89th Ct.
Medley, Florida 33178

Re: K260850
Trade/Device Name: Osteomni Spinal Cages System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE, MAX, MQP, PLR
Dated: March 16, 2026
Received: March 16, 2026

Dear Gulten Shurdom:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Brent Showalter -S

Brent Showalter, Ph.D.
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.	K260850 ?

Please provide the device trade name(s). ?

OSTEOMNI SPINAL CAGES SYSTEM

Please provide your Indications for Use below. ?

OSTEOMNI CERVICAL PEEK CAGES are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received at least six (6) weeks of prior non-operative treatment. Cervical Peek Cages facilitate intervertebral body fusion in the cervical spine and are placed via the anterior approach and packed with autogenous bone. OSTEOMNI CERVICAL PEEK CAGES are to be used with supplemental fixation.

OSTEOMNI CERVICAL Ti CAGES are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received at least six (6) weeks of prior non-operative treatment. Cervical Ti-Cages facilitate intervertebral body fusion in the cervical spine and are placed via the anterior approach and packed with autogenous bone. OSTEOMNI CERVICAL Ti CAGES are to be used with supplemental fixation.

OSTEOMNI LUMBAR PEEK CAGES are indicated for intervertebral body fusion at one or two contiguous levels in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) of lumbar spine with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received at least six (6) months of prior non-operative treatment. The devices are designed to be used with supplemental fixation and autograft/autologous bone graft to facilitate fusion for each spinal region.

OSTEOMNI LUMBAR Ti CAGES are indicated for intervertebral body fusion at one or two contiguous levels in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) of lumbar spine with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received at least six (6) months of prior non-operative treatment. The devices are designed to be used with supplemental fixation and autograft/autologous bone graft to facilitate fusion for each spinal region.

OSTEOMNI CERVICAL CORPECTOMY CAGE is intended for use in skeletally mature patients in the cervical spine (C2-T1) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

OSTEOMNI LUMBAR CORPECTOMY CAGE is intended for use in skeletally mature patients in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

OSTEOMNI CORPECTOMY CAGES are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

OSTEOMNI CORPECTOMY CAGES are intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material is optional.

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)	?
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

510(k) #:

510(k) Summary

Prepared on: 2026-05-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	OSTEOMNI INC.
Applicant Address	9956 NW 89TH CT MEDLEY, FL, 33178 MEDLEY FL 33178 United States
Applicant Contact Telephone	+1 7869993120
Applicant Contact	Mrs. GULTEN SHURDOM
Applicant Contact Email	cy@osteomni.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OSTEOMNI SPINAL CAGES SYSTEM
Common Name	Intervertebral Body Fusion Device; Vertebral Body Replacement Device
Classification Name	Intervertebral Body Fusion Device; Spinal Intervertebral Body Fixation Orthosis
Regulation Number	21 CFR 888.3080; 21 CFR 888.3060
Product Code(s)	ODP, OVE, MAX, MQP, PLR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K252686	EffortMed PEEK Cages & Corpectomy Cages	ODP, OVE, M

Device Description Summary

21 CFR 807.92(a)(4)

The OSTEOMNI SPINAL CAGES SYSTEM includes cervical intervertebral body fusion (IBFD), transforaminal lumbar interbody fusion (TLIF), and posterior lateral interbody fusion (PLIF) devices. The system was designed to restore height and lordotic angle in the spine. The main role of the cages is to help maintain the cleared disc space stable and intact, until a healthy bony fusion occurs between the adjoining vertebrae. To help achieve this, the inner chamber of the cage body is filled with bone graft before implantation.
The system also includes cervical and thoracolumbar corpectomy cages used in cervical spine (C2-T1) and in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to, tumors, fractures, and infections.
Implants are manufactured from PEEK and/or titanium alloy.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

OSTEOMNI CERVICAL PEEK CAGES are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received at least six (6) weeks of prior non-operative treatment. Cervical Peek Cages facilitate intervertebral body fusion in the cervical spine and are placed via the anterior approach and packed with autogenous bone. OSTEOMNI CERVICAL PEEK CAGES are to be used with supplemental fixation.
OSTEOMNI CERVICAL Ti CAGES are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received at least six (6) weeks of prior non-operative

treatment. Cervical Ti-Cages facilitate intervertebral body fusion in the cervical spine and are placed via the anterior approach and packed with autogenous bone. OSTEOMNI CERVICAL Ti CAGES are to be used with supplemental fixation.
OSTEOMNI LUMBAR PEEK CAGES are indicated for intervertebral body fusion at one or two contiguous levels in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) of lumbar spine with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received at least six (6) months of prior non-operative treatment. The devices are designed to be used with supplemental fixation and autograft/autologous bone graft to facilitate fusion for each spinal region.
OSTEOMNI LUMBAR Ti CAGES are indicated for intervertebral body fusion at one or two contiguous levels in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) of lumbar spine with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received at least six (6) months of prior non-operative treatment. The devices are designed to be used with supplemental fixation and autograft/autologous bone graft to facilitate fusion for each spinal region.
OSTEOMNI CERVICAL CORPECTOMY CAGE is intended for use in skeletally mature patients in the cervical spine (C2-T1) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.
OSTEOMNI LUMBAR CORPECTOMY CAGE is intended for use in skeletally mature patients in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.
OSTEOMNI CORPECTOMY CAGES are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.
OSTEOMNI CORPECTOMY CAGES are intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material is optional.

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

The indications for use for the OSTEOMNI SPINAL CAGES SYSTEM and the predicate device are the same.

Technological Comparison 21 CFR 807.92(a)(6)

Design: The designs of the Cervical and Lumbar PEEK Cages and the Corpectomy Cages are identical to the previously cleared predicate devices (K252686), with the exception of additional heights being added to one cervical cage design. This submission adds titanium alloy versions the Cervical and Lumbar Cages.
Sizes: Additional heights have been added to one of the cervical cage designs.
Material: Titanium alloy versions of the Cervical and Lumbar Cages are introduced in this submission.
Principles off operation: no difference

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

The designs of the Cervical and Lumbar PEEK Cages and the Corpectomy Cages are identical to the previously cleared predicate devices (K252686), with the exception of additional heights being added to one cervical cage design. This submission adds titanium alloy versions the Cervical and Lumbar Cages. The added designs do not represent new worst cases as compared to the previously cleared designs. Therefore, the non-clinical testing performed in support of the predicate device is applicable to the Osteomni devices.

Clinical Testing - Not applicable

Osteomni Spinal Cages System is substantially equivalent to the legally marketed predicate device identified above.