June 15, 2026

Medyssey Co, Ltd.
Hyokyeong Lee
Regulatory Affairs Specialist
129 Hanbang expo-ro
Jecheon-Si, Chungcheongbuk-do 27116
Republic Of Korea

Re: K260036
Trade/Device Name: NeckTune™ 3D SA Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: May 13, 2026
Received: May 13, 2026

Dear Ms. 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,

KATHERINE D. KAVLOCK -S

for
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.	K260036

Please provide the device trade name(s).

NeckTune™ 3D SA Cervical Cage

Please provide your Indications for Use below.

The NeckTune™ 3D SA Cervical Cage is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with associated radicular symptoms at one or two contiguous disc levels from C2–C3 through C7–T1.
DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.
The NeckTune™ 3D SA Cervical Cage is designed for use with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft to facilitate fusion.
The cage is intended to be used with the two provided fixation screws and, when used as intended, functions as a stand-alone interbody fusion device.
For cages with a lordotic angle of 20° or greater, use in the cervical spine requires combination with an FDA-cleared supplemental fixation system (e.g., cervical plates or cervical posterior fixation).
If the physician chooses to use the cage with fewer than two (2) screws, an FDA-cleared supplemental fixation system must be used.
Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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) #: K260036

510(k) Summary

Prepared on: 2026-06-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medyssey Co., Ltd.
Applicant Address	129 Hanbang expo-ro Jecheon-si Chungcheongbuk-do 27116 Korea, Republic of
Applicant Contact Telephone	+82-43-716-1014
Applicant Contact	Ms. Hyokyeong Lee
Applicant Contact Email	hyokyeong.lee@medyssey.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	NeckTune™ 3D SA Cervical Cage
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Integrated Fixation, Cervical
Regulation Number	888.3080
Product Code(s)	OVE, ODP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190546; K200543	NEXXT MATRIXX® Stand Alone Cervical System	OVE
K232348	RIGEL™ 3DR Standalone Anterior Cervical Interbody Fusion System	OVE
K241846	E3D™ -C Interbody System	ODP

Device Description Summary

21 CFR 807.92(a)(4)

The implants of the NeckTune™3D SA Cervical Cage consist of a spacer, screws, and a locking plate designed to prevent screw back-out. The locking plate is built into the spacer, forming an integrated Cage produced in a single 3D printing process. The spacer features a porous structure and a central through-hole intended to receive autograft or allograft bone to promote fusion. The NeckTune™ 3D SA Cervical Cage is available in various shapes and sizes to accommodate individual patient anatomy and pathology.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The NeckTune™ 3D SA Cervical Cage is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with associated radicular symptoms at one or two contiguous disc levels from C2–C3 through C7–T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.
The NeckTune™ 3D SA Cervical Cage is designed for use with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or autograft to facilitate fusion.
The cage is intended to be used with the two provided fixation screws and, when used as intended, functions as a stand-alone interbody fusion device.
For cages with a lordotic angle of 20° or greater, use in the cervical spine requires combination with an FDA-cleared supplemental fixation system (e.g., cervical plates or cervical posterior fixation).

If the physician chooses to use the cage with fewer than two (2) screws, an FDA-cleared supplemental fixation system must be used. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Indications for Use Comparison

21 CFR 807.92(a)(5)

NeckTune™ 3D SA Cervical Cage is substantially equivalent to the predicate devices based on a comparison of indications for use.

Technological Comparison

21 CFR 807.92(a)(6)

Evaluation of the technological characteristics of the NeckTune™ 3D SA Cervical Cage in comparison to the predicate devices demonstrated no differences affecting safety or effectiveness; therefore, the device is substantially equivalent to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The NeckTune™ 3D SA Cervical Cage has been tested in the following test:
- Static Compression Testing (ASTM F2077)
- Static Compression-Shear Testing (ASTM F2077)
- Static Torsion Testing (ASTM F2077)
- Dynamic Compression Testing (ASTM F2077)
- Dynamic Compression-Shear Testing (ASTM F2077)
- Dynamic Torsion Testing (ASTM F2077)
- Subsidence Testing (ASTM F2267)
- Expulsion Testing of Locking Plate (ASTM F543)
- Torsional Testing (ASTM F543)
- Driving & Removal Torque Testing (ASTM F543)
- Axial Pullout Testing (ASTM F543)

The results demonstrate that the NeckTune™ 3D SA Cervical Cage is substantially equivalent to predicate devices.

Not Applicable - No clinical data were necessary.

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