



September 29, 2026

Medyssey Co., Ltd.
Ms. Yujin Go
RA Part, R&D Dept
129 Hanbang Expo-Ro
Jecheon-Si, Chungcheongbuk-do 27116
Republic Of Korea

Re: K262726
Trade/Device Name: NeckTune™ SA Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: July 30, 2026
Received: July 31, 2026

Dear Ms. Go:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

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.

K262726

?

Please provide the device trade name(s).

?

NeckTune™ SA Cervical Cage

Please provide your Indications for Use below.

?

The NeckTune™ 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™ 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 a legally marketed 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, a legally marketed 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](#))

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510(k) #:

510(k) Summary

Prepared on: 2026-09-29

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. Yujin Go
Applicant Contact Email	yujin.go@medyssey.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	NeckTune™ 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
K260036	NeckTune™ 3D SA Cervical Cage	OVE
K2 223140	AEON-C™ Stand Alone System	OVE
K210573	Velofix SA Cervical Cage	OVE

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The NeckTune™ SA Cervical Cage is an anterior cervical interbody fusion device used to treat structural abnormalities resulting from degenerative disc disease. It is intended for use in skeletally mature patients at levels from C2–C3 through C7–T1.

The implants in the NeckTune™ SA Cervical Cage consist of three main components: The cage, screw, and locking plate. It comes various forms and sizes to accommodate individual patient anatomy and pathology. The cage is consisted a plate & a locking plate (Ti6Al4V ELI per ASTM F3001), a spacer (PEEK per ASTM F2026) and a radiographic marker (Tantalum per ASTM F560). Also, screws are made from Ti6Al4V ELI in compliance with (ASTM F136).

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The NeckTune™ 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™ 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 a legally marketed 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, a legally marketed 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\(a\)\(5\)](#)

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

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The NeckTune™ SA Cervical Cage and predicate device have similar technological characteristics, including dimensions, materials and technology. Performance testing demonstrates that the NeckTune™ SA Cervical Cage is substantially equivalent to the predicate devices. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Non-clinical performance testing was conducted to evaluate the mechanical safety of the subject device.

The subject device consists of components: a cage, a screw, and a locking plate.

The cage was tested in accordance with the following ASTM standards, as listed below.

- 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)

The screw and locking plate are shared with the cleared device (K260036) and are identical to those components; therefore, the following tests were not performed separately, and the subject device shares the same performance values as the predicate device.

- Expulsion Testing of Locking Plate (ASTM F543)
- Torsional Testing (ASTM F543)
- Driving & Removal Torque Testing (ASTM F543)
- Axial Pullout Testing (ASTM F543)

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