June 2, 2026

ZheJiang Decans Medical Devices Co., Ltd.
Haifeng Liu
RA Manager
No.2836,Xincheng Avenue,Gaozhao Street,Xiuzhou District
Jiaxing City, Zhejiang Province,314031,P.R. China
Jiaxing, Zhejiang
China

Re: K253195
Trade/Device Name: TAURUS Posterior Occipital-Cervico-Thoracic Spinal Systems
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: May 14, 2026
Received: May 15, 2026

Dear Haifeng Liu:

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,

COLIN O'NEILL -S

Colin O'Neill, M.B.E.
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.	K253195

Please provide the device trade name(s).

TAURUS Posterior Occipital-Cervico-Thoracic Spinal Systems

Please provide your Indications for Use below.

TAURUS Posterior Occipital-Cervico-Thoracic Spinal Systems is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine and the thoracic spine (Occiput-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The TAURUS Posterior Occipital-Cervico-Thoracic Spinal Systems is 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 spine in whom life expectancy is of insufficient duration to permit achievement of 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)
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) Summary

This 510(k) Summary has been prepared in accordance with 21 CFR §807.92.

Date of Preparation:15 September 2025

1. Submitter and Contact

Submitter

ZheJiang Decans Medical Devices Co., Ltd.

No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District, Jiaxing City, Zhejiang Province, 314031, P.R.China

Contact

Contact Person:Haifeng Liu, RA Manager

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Correspondent: Peiwen Feng, RA

Telephone:+86 18758326652

Email:pwfeng@decansmd.com

2. Identification of Subject Device

Trade Name: TAURUS Posterior Occipital-Cervico-Thoracic Spinal Systems

Regulation Number: 21 CFR 888.3075

Regulation Name: Posterior cervical screw system

Classification: II

Product Code: NKG

Associated Product Code:KWP

Review Panel: Orthopedic

Materials: Ti6Al4V

Patient contact: Bone and surrounding tissue

Contact duration:Permanent, >30 days

Sterilization method: Moist heat sterilization

Environment of Use: Healthcare facility/Hospital

Single Use: Yes

Provided status: Non-sterile

3. Identification of Predicate Device(s)

- **Primary predicate device**

Product Name	VERTEX™ Reconstruction System
Manufacturer	Medtronic Sofamor Danek USA, Inc.

510 (k)	K180851
Regulation number	21CFR888.3075
Regulation Name	Posterior Cervical Screw System
Regulation class	Class II
Product code	NKG,KWP
Review panel	Orthopedic

- **Additional predicate device**

Product Name	MOUNTAINEER OCT Spinal System, SUMMIT SI OCT Spinal Fixation System, SYMPHONY OCT System	Posterior cervical Spine System
510 (k)	K190895	K233078
Manufacturer	Medos International SARL %	Double Medical Technology, Inc.
Regulation number	21CFR888.3075	21CFR888.3075
Regulation Name	Posterior Cervical Screw System	Posterior Cervical Screw System
Regulation class	Class II	Class II
Product code	NKG,KWP,HWC,HRS	NKG,KWP
Review panel	Orthopedic	Orthopedic

- **Reference predicate**

Product Name	VERTEX® Reconstruction System
510 (k)	K110522
Manufacturer	Medtronic Sofamor Danek USA, Inc.
Regulation number	21CFR888.3050
Regulation Name	Spinal interlaminal fixation orthosis
Regulation class	Class II
Product code	KWP
Review panel	Orthopedic

4. Indications for Use

TAURUS Posterior Occipital-Cervico-Thoracic Spinal Systems is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine and the thoracic spine (Occiput-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis);

tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The TAURUS Posterior Occipital-Cervico-Thoracic Spinal Systems is 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 spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

5. Device Description

The TAURUS Posterior Occipital-Cervico-Thoracic Spinal Systems consists of rods, screws, connectors, crosslink, occipitocervical bone screws, occipital plates, laminar hooks and set screw. It can be firmly locked in multiple configurations and is suitable for each case to be customized with each structure. The implanted part can achieve stable fixation of two or more vertebral segments and can be removed when its stabilizing function is no longer needed.

TAURUS Posterior Occipital-Cervico-Thoracic Spinal Systems is a posterior cervical fixation system designed to effectively promote occipitocervical, cervical, and thoracic posterior fixation and fusion.

The implants are made from Ti-6Al-4V per ISO 5832-3. The implants and instruments are provided non-sterile.The implants are intended for single-use only, while the instruments are reusable.

6. SE Comparison of Indications for Use and Technological Characteristics

The subject device and predicate devices are equivalent in indications for use and technological characteristics.

The technological similarities identified between the subject and predicate devices are considered minor and won't impact substantial equivalence.

7. Test Summary

- **Standard Performance Test**

A series of side-by-side tests have been conducted on subject and predicate, in order to support mechanical equivalence, including following:

Four-point bending test (static&dynamic) per ASTM F2193

Driving torque test per ASTM F2193

Axial pullout strength test per ASTM F543

Torsional properties test per ASTM F2193

Static axial torque test per ASTM F1798

Static axial gripping capacity test per ASTM F1798

Flexion extension momen test per ASTM F1798

Axial compression bending test (static&dynamic) per ASTM F2706

Torsion test (static&dynamic) per ASTM F2706

Screw bending test (static&dynamic) per ASTM F2193

Static axial tensile bending test per ASTM F2706

- **Sterilization efficacy validation**

The recommended sterilization method for subject device is moist heat sterilization. The sterilization validation has been performed on an representative product in accordance with ISO 17665:2024. A sterility assurance level (SAL) of 10^{-6} has been demonstrated.

8. Performance-Clinical or Animal

No animal study data is submitted in this 510(k).

No clinical study data is submitted in this 510(k).

9. Conclusion

Comparison of indications for use, technological characteristics and nonclinical bench testing demonstrate the TAURUS Posterior Occipital-Cervico-Thoracic Spinal Systems is substantially equivalent to the predicate devices.