June 25, 2025

CG MedTech Co., Ltd.
Jeongah Kim
Official Correspondent
20, Sandan-ro 76beon-gil(Rd)
Uijeongbu-si, Gyeonggi-do 11781
South Korea

Re: K251725
Trade/Device Name: ANAX™ OCT Spinal System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior cervical screw system
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: June 5, 2025
Received: June 5, 2025

Dear Jeongah Kim:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.	K251725

Please provide the device trade name(s).

ANAX™ OCT Spinal System

Please provide your Indications for Use below.

ANAX™ OCT Spinal System 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 (C1 to C7) and the thoracic spine from T1-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. ANAX™ OCT Spinal System 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.

In order to achieve additional levels of fixation, ANAX™ OCT Spinal System may be connected to Perfix™ Spinal System and ANAX™ 5.5 Spinal System rods with the rod connectors. Transition rods with differing diameters may also be used to connect ANAX™ OCT Spinal System to Perfix™ Spinal System and ANAX™ 5.5 Spinal System.

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

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

510(k) Summary

Manufacturer:	CG MedTech Co., Ltd. 20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, 11781, Korea,
Sponsor:	CG MedTech Co., Ltd. 20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, 11781, Korea,
Sponsor Contact:	Jeongah Kim, RA Specialist +82 31 860 6845 jakim@cgmedt.com
Date Prepared:	June 05, 2025
Trade Name:	ANAX™ OCT Spinal System
Classification Name:	Spinal Interlaminal Fixation Orthosis
Classification:	Class II, 21 CFR 888.3075, Posterior cervical screw system
Common Name:	Occipito-cervico-thoracic Spinal Fixation System
Product Code:	NKG, KWP
Predicate Device:	ANAX™ OCT Spinal System (K150570, K183383) (primary) VERTEX SELECT® Reconstruction System (K110522, K123656)
Reference Devices:	ANAX™ 5.5 Spinal System (K132101, K143417, K162189, K173524, K231737)

Description of Device:

The ANAX™ OCT Spinal System is manufactured by CG MedTech Co., Ltd. The ANAX™ OCT Spinal System is for fixation the cervicocranium (Occiput/C2), the true subaxial region (C3/C6), and the cervicothoracic junction (C7 to T2) by one system. The ANAX™ OCT Spinal System consists of polyaxial screws, polyaxial shank screws, hooks, rods, set screws, transverse (cross) links and occipital plate. Connectors are also provided for surgical convenience. The ANAX™ OCT Spinal System allows surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The single-use ANAX™ OCT Spinal System components are supplied as non-sterile and are fabricated from medical grade titanium alloy (ASTM F136) and medical grade cobalt-chromium-molybdenum alloy (ASTM F1537). All polyaxial screws have self-tapping functions in the ANAX™ OCT Spinal System. Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the ANAX™ OCT Spinal System implants.

Indications for Use:

ANAX™ OCT Spinal System 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 (C1 to C7) and the thoracic spine from T1-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. ANAX™ OCT Spinal System is also in tended 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. In order to achieve additional levels of fixation, ANAX™ OCT Spinal System may be connected to Perfix™ Spinal System and ANAX™ 5.5 Spinal System rods with the rod connectors. Transition rods with differing diameters may also be used to connect ANAX™ OCT Spinal System to Perfix™ Spinal System and ANAX™ 5.5 Spinal System.

Substantial Equivalence:

The modified ANAX™ OCT Spinal System, incorporating cobalt-chromium-molybdenum (CoCr) rods, is substantially equivalent to the predicate devices—ANAX™ OCT Spinal System (K150570, K183383) and VERTEX SELECT® Reconstruction System (K110522, K123656)—in terms of design, mechanical performance, function, and intended use. The only modification is the addition of CoCr rods, which are identical in geometry and dimensions to the previously cleared titanium rods.

1. Comparison Technological Characteristics

The proposed device shares the following similarities with the predicate devices:

- Identical indications for use to the predicate devices.
- Equivalent overall construct design, dimensions, and components, with the only modification being the addition of CoCr rods.
- Cobalt-chromium-molybdenum (CoCr) rods exhibit higher tensile and yield strength compared to titanium (Ti) rods, resulting in comparable or superior material performance.
- CoCr rods are manufactured and processed using the same methods and surface treatments as the previously cleared Ti rods.
- Equivalent mechanical performance has been demonstrated through comparative material analysis and existing mechanical test data.

2. Performance Testing

The mechanical integrity of the CoCr rods was confirmed through comprehensive mechanical testing (e.g., ASTM F1717, F1798) and comparative analysis against the existing Ti rods, including evaluation of the worst-case configuration. All failure modes occurred at the screw–housing interface, not the rod itself. Comparative material analysis confirms that CoCr rods possess higher tensile and yield strength than Ti rods. Therefore, the addition of

CoCr rods does not raise new questions of safety or effectiveness.

3. Conclusion

The ANAX™ OCT Spinal System with CoCr rods is substantially equivalent to the predicate devices—ANAX™ OCT Spinal System (K150570, K183383) and VERTEX SELECT® Reconstruction System (K110522, K123656)—with respect to indications for use, design, technological characteristics, and performance. The addition of CoCr rods does not introduce new concerns regarding the safety or effectiveness of the device.