



November 12, 2025

icotec ag  
% Michael Coladonato  
Associate Director, Spine Regulatory Affairs  
MCRA, LLC  
803 7th Street, NW  
Washington, District of Columbia 20001

Re: K252327

Trade/Device Name: CMORE® CT System; CMORE® CT System Navigated Instruments

Regulation Number: 21 CFR 888.3075

Regulation Name: Posterior Cervical Screw System

Regulatory Class: Class II

Product Code: NKG, OLO

Dated: October 8, 2025

Received: October 8, 2025

Dear Justin Eggleton:

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](mailto: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.

K252327

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Please provide the device trade name(s).

?

CMORE® CT System;  
CMORE® CT System Navigated Instruments

Please provide your Indications for Use below.

?

## CMORE® CT System

The CMORE® CT System is 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 patients requiring adjuvant radiotherapy following spinal stabilization, metal markers at the screw tips can be used as fiducial markers in radiotherapy treatments (e.g., SBRT, proton therapy).

The CMORE® CT System is intended to provide immobilization and stabilization of spinal segments with anterior interbody support implanted at the same spinal level/s as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3):

- Traumatic spinal fractures and/or traumatic dislocations
- Instability or deformity
- Failed previous fusions (e.g. pseudarthrosis)
- Degenerative disease, including intractable radiculopathy and/or myelopathy
- Neck and/or arm pain of discogenic origin as confirmed by radiographic studies
- Degenerative disease of the facets with instability
- Patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression.

The CMORE® CT System is intended to be used with anterior interbody support implanted at the same spinal level/s with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

The CMORE® CT System may be connected to the VADER® Pedicle System using connectors.

## CMORE® CT System Navigated Instruments

CMORE® CT System Navigated Instruments are intended to be used during the preparation and placement of the CMORE® CT System during spinal surgery to assist the surgeon in precisely locating anatomical structures in open procedures. These instruments are designed for use with the Medtronic StealthStation® and Brainlab Navigation Systems which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT- or MR- based model, fluoroscopy images, or digitized landmarks of anatomy.

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)

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## 510(k) Summary

**Device Trade Name:** CMORE® CT System, CMORE® CT System Navigated Instruments

**Manufacturer:** icotec ag  
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Switzerland  
[www.icotec-medical.com](http://www.icotec-medical.com)

**Contact:** Michael Coladonato  
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**Prepared by:** MCRA, LLC  
803 7<sup>th</sup> Street, NW  
Washington, DC 20001  
Office: 202.552.5800

**Date Prepared:** 11/10/2025

**Classifications:** 21 CFR §888.3075, Posterior cervical screw system  
21 CFR §882.4560, Stereotaxic instrument

**Class:** II

**Product Codes:** NKG, OLO

**Primary Predicate:** EUROPA™ Posterior Cervical Fusion System (K242516)

**Additional Predicate:** CarboClear® Posterior Cervical Screw System (K233989)  
ExcelsiusHub™ (K231850)

**Reference Device:** SYMPHONY™ OCT System (K181949)

### Indications For Use:

#### CMORE® CT System

The CMORE® CT System is 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 patients requiring adjuvant radiotherapy following spinal stabilization, metal markers at the screw tips can be used as fiducial markers in radiotherapy treatments (e.g., SBRT, proton therapy).

The CMORE<sup>®</sup> CT System is intended to provide immobilization and stabilization of spinal segments with anterior interbody support implanted at the same spinal level/s as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3):

- Traumatic spinal fractures and/or traumatic dislocations
- Instability or deformity
- Failed previous fusions (e.g. pseudarthrosis)
- Degenerative disease, including intractable radiculopathy and/or myelopathy
- Neck and/or arm pain of discogenic origin as confirmed by radiographic studies
- Degenerative disease of the facets with instability
- Patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression.

The CMORE<sup>®</sup> CT System is intended to be used with anterior interbody support implanted at the same spinal level/s with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

The CMORE<sup>®</sup> CT System may be connected to the VADER<sup>®</sup> Pedicle System using connectors.

#### CMORE<sup>®</sup> CT System Navigated Instruments

CMORE<sup>®</sup> CT System Navigated Instruments are intended to be used during the preparation and placement of the CMORE<sup>®</sup> CT System during spinal surgery to assist the surgeon in precisely locating anatomical structures in open procedures. These instruments are designed for use with the Medtronic StealthStation<sup>®</sup> and Brainlab Navigation Systems which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT- or MR- based model, fluoroscopy images, or digitized landmarks of anatomy.

#### **Device Description:**

##### CMORE<sup>®</sup> CT System

The CMORE<sup>®</sup> CT System is a posterior cervical fixation system intended to provide structural stability and mechanical support to the cervical and upper thoracic spine. The CMORE<sup>®</sup> CT System is manufactured from Carbon/PEEK using a proprietary manufacturing process and is comprised of screws, rods, nut screws, and connectors as well as corresponding instruments.

##### CMORE<sup>®</sup> CT System System Navigated Instruments

The CMORE<sup>®</sup> CT System Navigated Instruments are reusable instruments used for the preparation and placement of FDA-cleared spinal bone screws during spinal surgery to assist the surgeon in precisely locating anatomical structures. These instruments are designed to be

used with the Medtronic StealthStation® and Brainlab Navigation Systems. The instruments include awls, drills, probes, taps, drivers, and adapters.

**Predicate Device:**

CMORE® CT System

icotec ag submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the CMORE® CT System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: EUROPA™ Posterior Cervical Fusion System (K242516)

Additional Predicate: CarboClear® Posterior Cervical Screw System (K233989)

Reference Device: SYMPHONY™ OCT System (K181949)

CMORE® CT System Navigated Instruments

icotec ag submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the CMORE® CT System Navigated Instruments are substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Additional Predicate: ExcelsiusHub™ (K231850)

**Performance Testing Summary:**

CMORE® CT System

The mechanical performance profile of the CMORE® CT System was assessed through static and dynamic testing in accordance with the following test methods:

- Static and dynamic compression bending per ASTM F1717
- Static torsion strength testing per ASTM F1717
- Static axial and torque gripping capacity per ASTM F1798
- Static flexion/extension bending strength per ASTM F1798

The summative usability evaluation was conducted on the CMORE® CT System markers as part of the final assessment of cervical posterior fixation implants. The evaluation took place in a wetlab environment using cadaver specimens and various imaging modalities. Orthopedic surgeons and radiation oncologists participated by providing feedback on implant visibility and imaging compatibility.

Results demonstrated that tantalum and titanium markers provided radiographic visibility with CT and MRI imaging modalities. The usability testing found no safety-related issues or deviations during the evaluation.

Overall, the implant markers were confirmed to be safe and effective for intra- and postoperative imaging, supporting their use in the device as intended.

### CMORE<sup>®</sup> CT System Navigated Instruments

The CMORE<sup>®</sup> CT System Navigated Instruments have been tested per ASTM F2554.

#### **Substantial Equivalence:**

The CMORE<sup>®</sup> CT System is composed of Carbon/PEEK, while the primary predicate device (K242516) is made of a Molybdenum-Rhenium composite. An additional predicate device (K233989) made of CFR-PEEK has been cleared for cervical and upper thoracic spine applications. Despite the differences in material composition, the technological characteristics of the CMORE<sup>®</sup> CT System do not raise new safety or effectiveness concerns.

The CMORE<sup>®</sup> CT System Navigated instruments and the corresponding additional predicate device (K231850) both use instrument mounted tracking arrays for navigation and allow for integration with CT or fluoroscopy-based imaging for anatomical referencing. The subject device and the predicate device have different navigation system compatibility, but this does not raise questions of safety and effectiveness.

The subject devices were demonstrated to be substantially equivalent to the predicate devices cited in the section above with respect to intended use, indications, design, and performance.

#### **Conclusion:**

The subject devices and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. The CMORE<sup>®</sup> CT System and the CMORE<sup>®</sup> CT System Navigated Instruments are as safe, as effective, and performs as well as, or better, than the predicate devices.