March 16, 2026

CarboFix Orthopedics , Ltd.
Yael Rubin
Director of Regulatory Affairs
11 Ha'Hoshlim St.
Herzeliya, 4672411
Israel

Re: K254045
Trade/Device Name: CarboClear® Posterior Cervical Screw System; CarboClear® Hybrid Posterior Cervical Screw System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG
Dated: December 16, 2025
Received: December 17, 2025

Dear Yael Rubin:

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.	K254045

Please provide the device trade name(s).

CarboClear® Posterior Cervical Screw System ;
CarboClear® Hybrid Posterior Cervical Screw System

Please provide your Indications for Use below.

The CarboClear® Posterior Cervical Screw System / CarboClear® Hybrid Posterior Cervical Screw 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.

The CarboClear® Posterior Cervical Screw System / CarboClear® Hybrid Posterior Cervical Screw 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 and the upper thoracic spine (T1 to T3):
- Traumatic spinal fractures and/or dislocations
- Instability and 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 CarboClear® Posterior Cervical Screw System / CarboClear® Hybrid Posterior Cervical Screw 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.

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) Summary

CarboFix Orthopedics Ltd.

CarboClear® Posterior Cervical Screw System
CarboClear® Hybrid Posterior Cervical Screw System

Applicant Name

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Contact Person

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Date Prepared

December 2025

Trade/Proprietary Name

CarboClear® Posterior Cervical Screw System
CarboClear® Hybrid Posterior Cervical Screw System

Common Name

Posterior, Cervical Spine Fixation

Regulation Number and Device Class

Class II; 21 CFR §888.3075

Product Code, Regulatory Description and Review Panel

NKG, Posterior Cervical Screw System, Orthopedic

Predicate Devices

Primary Predicate Device:

- CMORE® CT System (icotec; K252327)

Additional Predicate Devices:

- CarboClear® Posterior Cervical Screw System (CarboFix Orthopedics Ltd.;K233989)
- INFINITY™ OCT System (Medtronic; K163375)

Reference Device:

- CarboClear® Hybrid Pedicle Screw System (CarboFix Orthopedics Ltd.; K240846, K243106)

Indications for Use

The CarboClear® Posterior Cervical Screw System / CarboClear® Hybrid Posterior Cervical Screw 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.

The CarboClear® Posterior Cervical Screw System / CarboClear® Hybrid Posterior Cervical Screw 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 and the upper thoracic spine (T1 to T3):

- Traumatic spinal fractures and/or dislocations
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The CarboClear® Posterior Cervical Screw System / CarboClear® Hybrid Posterior Cervical Screw 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.

System Description

CarboClear® Posterior Cervical Screw System ("CarboClear® System") and CarboClear® Hybrid Posterior Cervical Screw System ("CarboClear® Hybrid System") are composed of implants in various dimensions, used to build a spinal construct; and of a set of instruments, intended to assist in the insertion and placement of the implants.

The screws incorporated into the systems are made of carbon fiber-reinforced polyetheretherketone (CFR-PEEK), with the CarboClear® Hybrid screws incorporating titanium alloy tulip. The screws threaded portion, and spherical head are encased within a thin titanium shell, and they may include a tantalum marker. The CarboClear® posterior cervical screws are used with CFR-PEEK set screw, and the CarboClear® Hybrid posterior cervical screws are used with a titanium alloy set screw. All screws are used with CarboClear® CFR-PEEK rods. CarboClear® titanium alloy rods are also offered.

The implants are supplied sterile, and are intended for single use.

Purpose of Submission

Modification to the previously cleared CarboClear® Posterior Cervical Screw System (K233989) – modification to indications for use and addition of implants, and addition of CarboClear® Hybrid Posterior Cervical Screw System.

Performance Data

Performance characteristics included static and dynamic compression bending tests according to ASTM F1717, ASTM F1798 (flexion-extension and axial and torsional gripping capacity), and wear evaluation. The results of the tests are comparable to those of the predicate devices, demonstrating substantially equivalent performance of the subject and predicate devices.

Substantial Equivalence

The intended use, design, dimensions, materials, technological characteristics, principles of operation, and performance of the CarboClear®- and CarboClear® Hybrid Posterior Cervical Screw Systems are substantially equivalent to those of the predicate devices, as applicable.

Conclusion

Based on the information provided in this Premarket Notification, the CarboClear®- and CarboClear® Hybrid Posterior Cervical Screw Systems are substantially equivalent to their predicate devices.