March 27, 2024

CarboFix Orthopedics Ltd.
Batya Cohen
Regulatory Affairs
11 Ha'Hoshlim Street
Herzeliya, 4672411
Israel

Re: K233989
Trade/Device Name: CarboClear® Posterior Cervical Screw System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG
Dated: February 28, 2024
Received: February 28, 2024

Dear Batya Cohen:

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.

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 FDA

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233989

Device Name

CarboClear® Posterior Cervical Screw System

Indications for Use *(Describe)*

The CarboClear® 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.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

CarboFix Orthopedics Ltd.

CarboClear® Posterior Cervical Screw System

Applicant Name

CarboFix Orthopedics, Ltd.

11 Ha'hoshlim St., Herzeliya 4672411, Israel

Contact Person

Batya Cohen

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Tel: +972 9 9511511, Fax: +972 9 9548939

Date Prepared

December 2023

Trade/Proprietary Name

CarboClear® Posterior Cervical Screw System

Common Name

Posterior, Cervical Spine Fixation

Classification Name

Orthopedic; Posterior Cervical Screw System (21 CFR §888.3075; Class II; Product Code NKG).

Predicate Devices

Primary Predicate:

- Synapse Occipital-Cervical-Thoracic (OCT) System (DePuy Synthes Spine; K142838)

Additional Predicates:

- Mesa Mini Spinal System (K2M, Inc.; K153370)
- CarboClear® X Pedicle Screw System (CarboFix Orthopedics Ltd.; K210716)

Reference:

- CarboClear® Cervical Cage and VBR System (CarboFix Orthopedics Ltd.; K222874)

Indications for Use

The CarboClear® 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.

System Description

The CarboClear® Posterior Cervical Screw System ("CarboClear® System") is 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 CarboClear® System is a posterior, cervical screw fixation system, intended to provide immobilization and stabilization of cervical spinal segments in oncological patients.

The CarboClear® System implants include posterior screws, rods and locking elements (set screw). The implants are made mainly of carbon fiber-reinforced polyetheretherketone (CFR-PEEK). The threaded portion and the spherical head of the screw are encased within a thin titanium shell, and may include a tantalum marker.

Substantial Equivalence

The CarboClear® Posterior Cervical Screw System indications for use are a sub-group of the indications for use of the primary predicate, referring to use of the system 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.

The CarboClear® Posterior Cervical Screw System design, materials, technological characteristics, and principles of operation are substantially equivalent to those of the predicate devices, as applicable.
Performance characteristics included static and dynamic tests according to ASTM F1717, ASTM F1798, ASTM F2193, ASTM F1044. The test results are comparable to those of predicate devices, as applicable, demonstrating that the device is safe and effective for its intended use.

CarboClear® Posterior Cervical Screw System is part of the CarboClear Pedicle Screw Systems family.

Conclusion

Based on the information provided in this Premarket Notification and non-clinical performance data, the subject CarboClear® Posterior Cervical Screw System is substantially equivalent to its predicate devices.