Carbofix Orthopedics Ltd.
Hila Wachsler-Avrahami
Regulatory Affairs
11 Ha'Hoshlim St.
Herzeliya, 4672411
Israel

November 5, 2024

Re: K243106
Trade/Device Name: CarboClear® Hybrid Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: September 30, 2024
Received: September 30, 2024

Dear Hila Wachsler-Avrahami:

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.11.05 09:27:13 -05'00'

for

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)*

K243106

Device Name

CarboClear® Hybrid Pedicle Screw System

Indications for Use *(Describe)*

CarboClear® Hybrid Pedicle Screw System (DDD)
The CarboClear® Hybrid Pedicle Screw System is intended to provide rigid immobilization and stabilization of lumbar and/or sacral segments as an adjunct to fusion in patients with degenerative disc disease (DDD) at up to three levels from L2 to S1, with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have at least six months of non-operative treatment.
The CarboClear® Hybrid Pedicle Screw System is intended to be used with intervertebral body fusion device/s implanted at the same spinal level/s with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

CarboFix Orthopedics Ltd.

CarboClear® Hybrid Pedicle Screw System

APPLICANT NAME

CarboFix Orthopedics Ltd.
11 Ha'hoshlim St., Herzeliya 4672411, Israel
Tel: +972 9 9511511, Fax: +972 9 9548939

CONTACT PERSON

Hila Wachsler-Avrahami
CarboFix Orthopedics Ltd.
11 Ha'hoshlim St., Herzeliya 4672411, Israel
Tel: +972 9 9511511, Fax: +972 9 9548939

DATE PREPARED

September 30, 2024

TRADE/PROPRIETARY NAME

CarboClear® Hybrid Pedicle Screw System

COMMON NAME

Pedicle Screw System

REGULATION NUMBER AND DEVICE CLASS

Class II; 21 CFR §888.3070

PRODUCT CODE, REGULATORY DESCRIPTION AND REVIEW PANEL

NKB; Thoracolumbosacral Pedicle Screw System; Orthopedic

PREDICATE DEVICES

Primary Predicate Device:

CarboClear® X Pedicle Screw System (CarboFix Orthopedics Ltd.; K233793)

Additional Predicate Devices:

- CarboClear® Hybrid Pedicle Screw System (CarboFix Orthopedics Ltd.; K240846)
- CD HORIZON® Spinal System (Medtronic Sofamor Danek; K082236 and more)
- S4® Spinal System (Aesculap Spine; K130291 and more)
- Dymaxeon Spine System (Back 2 Basics Direct, LCC; K192930)

INTENDED USE/INDICATIONS FOR USE

CarboClear® Hybrid Pedicle Screw System

The CarboClear® Hybrid Pedicle Screw System is intended to provide rigid immobilization and stabilization of lumbar and/or sacral segments as an adjunct to fusion in patients with degenerative disc disease (DDD) at up to three levels from L2 to S1, with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have at least six months of non-operative treatment.

The CarboClear® Hybrid Pedicle Screw System is intended to be used with intervertebral body fusion device/s implanted at the same spinal level/s with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

SYSTEM DESCRIPTION

The CarboClear® Hybrid Pedicle Screw 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® Hybrid Pedicle Screws, including CarboClear® Hybrid Fenestrated Screws, are made of carbon fiber-reinforced polyetheretherketone (CFR-PEEK), with titanium alloy tulip. Their threaded portion is encased within a thin titanium shell. They are used with a compatible titanium alloy set screw, and with CarboClear CFR-PEEK rods. The implants may include tantalum markers. CarboClear titanium alloy rod is also offered.

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

The CarboClear® Hybrid implants may be implanted in an open approach or using a minimally invasive surgery (MIS) approach.

PURPOSE OF SUBMISSION

Expansion of indications for use.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Compared to the cleared CarboClear® Hybrid Pedicle Screw System (K240846), the subject CarboClear® Hybrid System includes longer rods.

PERFORMANCE DATA

Previously conducted performance testing of the CarboClear® Hybrid Pedicle Screw System included static and dynamic tests according to ASTM F1717, as well as static flexion-extension moment test, axial gripping capacity test, and torsional gripping capacity test according to ASTM F1798. The results of the tests were shown to be comparable to those of predicate devices. No new performance testing was necessary to support the current submission.

SUBSTANTIAL EQUIVALENCE

The intended use, design, dimensions, materials, technological characteristics, principles of operation, and performance of the subject CarboClear® Hybrid Pedicle Screw System are substantially equivalent to those of the predicate devices.

CONCLUSION

Based on the information provided in this 510(k) Premarket Notification, the subject CarboClear® Hybrid Pedicle Screw System is substantially equivalent to its predicate devices.