



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

January 10, 2024

Re: K233944

Trade/Device Name: CarboClear® X Pedicle Screw System; CarboClear® X Navigated Instruments
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, OLO
Dated: December 14, 2023
Received: December 14, 2023

Dear Hila Wachslar-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).

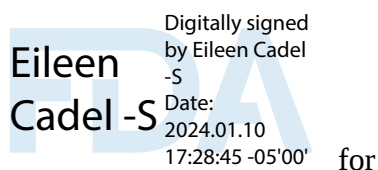
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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,

Digitally signed
by Eileen Cadel
-S
Date:
2024.01.10
17:28:45 -05'00' for

A digital signature block for Eileen Cadel-S. It includes the text "Digitally signed by Eileen Cadel -S", a date and time stamp "Date: 2024.01.10 17:28:45 -05'00'", and the word "for". The signature itself is a large, stylized, light blue "E" that partially overlaps the text.

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

Submission Number (if known)

K233944

Device Name

CarboClear® X Pedicle Screw System;
CarboClear® X Navigated Instruments

Indications for Use (Describe)

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

CarboClear® X Navigated Instruments are intended to be used during the preparation and placement of CarboClear® X Pedicle Screws during spinal surgery to assist the surgeon in precisely locating anatomical structures. CarboClear® X Navigated Instruments are designed for use with the Medtronic StealthStation® System, which is 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 vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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.

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CARBOFIX ORTHOPEDICS LTD.
CARBOCLEAR® X PEDICLE SCREW SYSTEM

510(k) Summary

CarboFix Orthopedics Ltd.

CarboClear® X Pedicle Screw System, CarboClear® X Navigated Instruments

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

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

Date Prepared

December 14, 2023

Trade/Proprietary Name

1. CarboClear® X Pedicle Screw System
2. CarboClear® X Navigated Instruments

Common Name

1. Pedicle Screw System
2. Stereotaxic Instrument

Regulation Number and Device Class

1. Class II; 21 CFR §888.3070
2. Class II; 21 CFR §882.4560

Product Code, Regulatory Description and Review Panel

1. NKB; Thoracolumbosacral Pedicle Screw System; Orthopedic
2. OLO; Orthopedic Stereotaxic Instrument; Orthopedic

Predicate Devices

Primary Predicate Device:

- CarboClear® Pedicle Screw System (CarboFix Orthopedics Ltd.; K232341)

Additional Predicate Devices:

- CarboClear® X Pedicle Screw System; CarboClear® X Navigated Instruments (CarboFix Orthopedics Ltd.; K210716, K231280)
- CarboClear® Pedicle Screw System (CarboFix Orthopedics Ltd.; K173487, K201926 and more)
- CD HORIZON® Spinal System (Medtronic Sofamor Danek; K082236 and more)
- S4® Spinal System (Aesculap Spine; K130291 and more)

Intended Use/Indications for Use

CarboClear® X Pedicle Screw System

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

CarboClear® X Navigated Instruments

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System Description

The ***CarboClear® X 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 implants include pedicle screws, rods, and a locking element (set screw). They are made of carbon fiber-reinforced polyetheretherketone (CFR-PEEK). The threaded portion of the pedicle screws is encased within a thin titanium shell. The implants may include tantalum markers. Titanium alloy rod is also available.

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

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

The ***CarboClear® X Navigated Instruments*** are manually operated instruments, intended to be used with Medtronic's StealthStation® Navigation System, to assist surgeons in precisely locating anatomical structures for preparation and placement of CarboClear® X pedicle screws during spinal surgery.

Purpose of Submission

Modification to the previously cleared CarboClear® Pedicle Screw System (K232341).

Comparison of Technological Characteristics with Predicate Devices

- The subject CarboClear® X Pedicle Screw System has the same indications for use as the primary predicate device (K232341). It differs from the primary predicate in the device locking mechanism.
- The subject CarboClear® X pedicle screws, rods and locking element are identical to the corresponding implant components which were cleared as part of the CarboClear X Pedicle Screw System (K210716 and K231280). Specifically, they are made of the same materials, have the same design and dimensions, and have the same locking mechanism.
- The subject CarboClear® X Navigated Instruments are identical to those cleared in K210716 and K231280.

Performance Data

Performance characteristics previously presented in prior submissions for the CarboClear® X Pedicle Screw System (K210716 & K173487) included static compression bending, dynamic compression bending, and static torsion according to ASTM F1717, as well as static flexion-extension, axial grip, and torsional grip according to ASTM F1798. 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 subject CarboClear® X Pedicle Screw System, including CarboClear® X Navigated Instruments, are substantially equivalent to those of the predicate devices.

Conclusion

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