



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

October 10, 2023

Re: K232341

Trade/Device Name: CarboClear® Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: August 4, 2023
Received: August 4, 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 -
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Date: 2023.10.10
16:41:46 -04'00'

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

Indications for Use

510(k) Number (if known)

K232341

Device Name

CarboClear® Pedicle Screw System

Indications for Use (Describe)

The CarboClear® 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® 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.

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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510(k) Summary

CarboFix Orthopedics Ltd. CarboClear® Pedicle Screw System,

Applicant Name

CarboFix Orthopedics, Ltd.

11 Ha'hoshlim St., Herzeliya 4672411, Israel

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

August 4, 2023

Trade/Proprietary Name

CarboClear® Pedicle Screw System

Common Name

Pedicle Screw System

Regulation Number and Device Class

Class II; 21 CFR §888.3070

Product Code and Review Panel

NKB; Thoracolumbosacral Pedicle Screw System; Orthopedic

Predicate DevicesPrimary Predicates:

- Mesa Spinal System (K2M, Inc.; K181119 and more)

Additional Predicates:

- CarboClear Pedicle Screw System, (CarboFix Orthopedics Ltd., K173487 and more).
- CD HORIZON® Spinal System (Medtronic Sofamor Danek; K0822236 and more)
- Synergy VLS Spinal System (Interpore Cross International; K010515 and more)
- S4® Spinal System (Aesculap Spine; K130291 and more)
- REVERE® Stabilization System (Globus Medical, Inc.; K133350 and more)

Indications for Use

The CarboClear® 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® 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.

System Description

The CarboClear® 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® implants include pedicle screws, rods and locking elements. The implants 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 include tantalum markers.

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

Purpose of Submission

To seek additional pedicle screw indication for degenerative disc disease (DDD).

Performance Data

Performance testing previously presented in prior submissions for the CarboClear Pedicle Screw System included static and dynamic tests according to ASTM F1717, and tests according to ASTM F1798, ASTM F2193, ASTM F543; as well as fatigue lateral bending-axial rotation test and rod creep test. The test results were found to be comparable to those of predicate devices, as applicable, demonstrating substantially equivalent mechanical performance of the subject system.

Clinical data for the CarboClear® Pedicle Screw System was presented for the target population specified in the indications for use statement, and supports the substantially equivalent performance of the subject system.

Substantial Equivalence

The CarboClear® Pedicle Screw System intended use, design, technological characteristics, material, principles of operation and performance are substantially equivalent to those of the predicate devices, as applicable.

Conclusion

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