August 7, 2020

CarboFix Orthopedics Ltd.
Ms. Hila Wachsler-Avrahami
Regultory Affairs
11 Ha'hoshlim St.
Herzeliya, 4672411
Israel

Re: K201926
Trade/Device Name: CarboClear® Pedicle Screw System, CarboClear® II Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: July 8, 2020
Received: July 10, 2020

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.B.E.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K201926

Device Name

CarboClear® Pedicle Screw System

Indications for Use *(Describe)*

The CarboClear® Pedicle 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 thoracic and lumbar 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K201926

Device Name

CarboClear® II Pedicle Screw System

Indications for Use *(Describe)*

The CarboClear® II Pedicle 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 thoracic and lumbar 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® Pedicle Screw System

& CarboClear® II 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

July 8, 2020

Trade/Proprietary Name

1. CarboClear® Pedicle Screw System
2. CarboClear® II Pedicle Screw System

Common Name

Pedicle Screw System

Regulation Number and Device Class

21 CFR §888.3070; Class II

Product Code, Regulatory Description and Review Panel

NKB; Thoracolumbosacral pedicle screw system; Orthopedic

Predicate Devices

Primary Predicate Device:

1. CarboClear® Pedicle Screw System (CarboFix Orthopedics Ltd.; K173487)

Additional Predicate Devices:

- CarboClear® II Pedicle Screw System (CarboFix Orthopedics Ltd.; K200519)
- Mesa Spinal System (K2M, Inc.; K052398 and more)
- CD HORIZON® Spinal System (Medtronic Sofamor Danek; K981676 and more)

Intended Use/Indications for Use

1. CarboClear® Pedicle Screw System

The CarboClear® Pedicle 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

2. CarboClear® II Pedicle Screw System

The CarboClear® II Pedicle 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

System Description

The CarboClear® and CarboClear® II Pedicle Screw Systems 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 implants include pedicle screws, rods, locking elements and transverse connectors. 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, and includes a small tantalum marker.

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

Purpose of Submission

The purpose of this Special 510(k) Premarket Notification is to add pedicle screw sizes to the CarboClear® and CarboClear® II Pedicle Screw Systems.

Performance Data and Substantial Equivalence

The intended use, design, material, dimensions, technological characteristics, and principles of operation of the subject CarboClear® and CarboClear® II Pedicle Screw Systems are substantially equivalent to those of the predicate devices.

Performance characteristics included tests according to ASTM F1717, ASTM F1798, ASTM F2193 and ASTM F543. The results of the tests are comparable to those of the predicate devices, as applicable, demonstrating substantially equivalent mechanical performance of the subject device.

Conclusion

Based on the information provided in this Premarket Notification, the subject CarboClear® Pedicle Screw System and CarboClear® II Pedicle Screw System are substantially equivalent to their predicate devices.