October 11, 2019

CarboFix Orthopedics, Ltd.
Ms. Yael Rubin
Director of Regulatory Affairs
11 Ha'hoshlim St.
Herzeliya 4672411
Israel

Re: K192214
Trade/Device Name: CarboClear® VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: August 13, 2019
Received: August 15, 2019

Dear Ms. Rubin:

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,

for Ronald P. Jean, PhD
Director (Acting)
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K192214

Device Name
CarboClear® VBR System

Indications for Use *(Describe)*

The CarboClear Vertebral Body Replacement (VBR) System is intended for use during open surgical procedures in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (e.g., fracture).
The CarboClear Vertebral Body Replacement device is intended to be used with supplemental internal spinal fixation systems that have been labeled for use in the thoracic and lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).
The use of allograft or autograft with the CarboClear Vertebral Body Replacement device is optional.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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® VBR System

Applicant Name

CarboFix Orthopedics, Ltd.

11 Ha'hoshlim St., Herzeliya 4672411, Israel

Contact Person

Yael Rubin

CarboFix Orthopedics, Ltd.

11 Ha'hoshlim St., Herzeliya 4672411, Israel

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

Date Prepared

October 2019

Trade/Proprietary Name

CarboClear® VBR System

Common Name

Spinal Vertebral Body Replacement Device

Classification Name

Spinal intervertebral body fixation orthosis (21 CFR §888.3060; Class II; Product Code MQP).

Predicate Devices

Primary

- Giza® Vertebral Body Replacement (Eden Spine, LLC; K112429, and more)

Additional

- X-MESH™ Cage System (DePuy Spine; K173787, and more)
- Ocelot Stackable Cage System (DePuy Spine; K140759, and more)
- Bengal Cage System (DePuy Synthes Spine; K073649, and more)
- VERTE-STACK™ (Medtronic Sofamor Danek; K070173, and more)

Reference

- CarboClear Pedicle Screw System (CarboFix Orthopedics Ltd.; K173487, K182377)
- FORZA® Spacer System (Orthofix Inc.; K152475, and more)

Indications for Use

The CarboClear Vertebral Body Replacement (VBR) System is intended for use during open surgical procedures in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (*e.g.*, fracture).

The CarboClear Vertebral Body Replacement device is intended to be used with supplemental internal spinal fixation systems that have been labeled for use in the thoracic and lumbar spine (*i.e.*, posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

The use of allograft or autograft with the CarboClear Vertebral Body Replacement device is optional.

System Description

The CarboClear VBR System comprises implants (spacers) in different dimensions, and instruments.

The CarboClear VBR spacers are made of carbon fiber reinforced polyetheretherketone (CFR-PEEK), with titanium alloy endplates.

Substantial Equivalence

The CarboClear VBR System intended use, 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 axial compression and torsion testing per ASTM F 2077, expulsion testing, and endplate shear strength testing. Performance characteristics are comparable to those of predicate devices (as applicable), thus demonstrating that the device is substantially equivalent to the predicates.

In addition, bacterial endotoxin testing was conducted for the CarboClear System.