July 26, 2023

CarboFix Orthpedics Ltd.
Yael Rubin
Director of Regulatory Affairs
11 Ha'Hoshlim Street
Herzeliya, 4672411
Israel

Re: K222874
Trade/Device Name: CarboClear® Cervical Cage System, CarboClear® Cervical VBR System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, PLR
Dated: June 14, 2023
Received: June 14, 2023

Dear Yael 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,

Brent Showalter -S

Brent Showalter, Ph.D.
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)*
K222874

Device Name
CarboClear® Cervical Cage System

Indications for Use *(Describe)*

The CarboClear Cervical Cage System is indicated for intervertebral body fusion procedures of the cervical spine in skeletally mature patients with degenerative disc disease (DDD) at levels C2 – T1. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
The implants are to be implanted via an open, anterior approach and packed with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.
This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine.
Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with the CarboClear Cervical Cage System.

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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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)*
K222874

Device Name
CarboClear® Cervical VBR System

Indications for Use *(Describe)*

The CarboClear Cervical Vertebral Body Replacement (VBR) System Spacers are vertebral body replacement devices intended for use in the cervical spine (C2 – T1).
The CarboClear Cervical VBR devices are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The spacers are 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 cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.
The devices are intended to be used with supplemental internal spinal fixation systems that have been labeled for use in the cervical spine (i.e., posterior screw and rod systems, and anterior plate systems).

When used at more than two levels, supplemental fixation should include posterior fixation.
The use of allograft or autograft with the CarboClear Cervical VBR 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.

510(K) Summary

CarboFix Orthopedics Ltd.

CarboClear® Cervical Cage System; CarboClear® Cervical 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

September 2022

Trade/Proprietary Name

1. CarboClear® Cervical Cage System
2. CarboClear® Cervical VBR System

Common Name

1. Intervertebral Body Fusion Device - Cervical
2. Spinal Vertebral Body Replacement Device - Cervical

Regulation Number and Device Class

1. 21 CFR §888.3080; Class II
2. 21 CFR §888.3060; Class II

Product Code and Review Panel

1. ODP; Orthopedic
2. PLR; Orthopedic

Predicate Devices

Primary

1. **For CarboClear Cervical Cage System** - ALTA Cervical Interbody Spacer (Astura Medical; K160154, and more)
2. **For CarboClear Cervical VBR System** - HAWKEYE™ Vertebral Body Replacement (VBR) System (Choice Spine; K183588)

Additional

1. CarboClear Lumbar Cage System (CarboFix Orthopedics Ltd.; K193378, K203683)
2. CarboClear VBR System (CarboFix Orthopedics Ltd.; K192214)

Indications for Use

CarboClear Cervical Cage System

The CarboClear Cervical Cage System is indicated for intervertebral body fusion procedures of the cervical spine in skeletally mature patients with degenerative disc disease (DDD) at levels C2 – T1. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The implants are to be implanted via an open, anterior approach and packed with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.
This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine.
Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with the CarboClear Cervical Cage System.

CarboClear Cervical VBR System

The CarboClear Cervical Vertebral Body Replacement (VBR) System Spacers are vertebral body replacement devices intended for use in the cervical spine (C2 – T1).
The CarboClear Cervical VBR devices are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The spacers are 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 cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.
The devices are intended to be used with supplemental internal spinal fixation systems that have been labeled for use in the cervical spine (*i.e.*, posterior screw and rod systems, and anterior plate systems).

When used at more than two levels, supplemental fixation should include posterior fixation.
The use of allograft or autograft with the CarboClear Cervical VBR device is optional.

System Description

1. CarboClear Cervical Cage System is composed of implants of various sizes, and of instruments.

   The CarboClear Cervical Cage is made of carbon fiber-reinforced polyetheretherketone (CFR-PEEK), with titanium alloy endplates.

2. The CarboClear Cervical VBR System is composed of implants (spacers) in various sizes, and of instruments.

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

Performance Data

Performance characteristics, including static and dynamic axial compression tests (according to ASTM F2077); static and dynamic compression-shear tests (according to ASTM F2077); static and dynamic torsion tests (according to ASTM F2077); wear debris evaluation; and subsidence test (according to ASTM F2267), as applicable to each of the devices, are comparable to those of predicate devices (where applicable), thus demonstrating that the devices are safe and effective for their intended use.

Substantial Equivalence

The CarboClear Cervical Cage and Cervical VBR Systems intended use, design, dimensions, materials, technological characteristics, and principles of operation are substantially equivalent to those of the predicate devices, as applicable.

Conclusion

Based on the information provided in this 510(k) Premarket Notification, the subject CarboClear Cervical Cage and Cervical VBR Systems are substantially equivalent to their predicate devices.