March 2, 2020

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

Re: K193378
Trade/Device Name: CarboClear® Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 3, 2019
Received: December 5, 2019

Dear Ms. 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,

Brent L. Showalter, PhD
Assistant 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)*

K193378

Device Name
CarboClear® Lumbar Cage System

Indications for Use *(Describe)*

The CarboClear® Lumbar Cage System is indicated for intervertebral body fusion of the lumbar spine in skeletally mature patients with degenerative disc disease (DDD), at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The patients may also have up to Grade I spondylolisthesis at the involved levels.
CarboClear® Lumbar Cage System is intended for use with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and with supplemental fixation cleared for use in the lumbosacral spine.
Patients should have at least six months of non-operative treatment prior to surgery.

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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K193378
510(K) Summary

CarboFix Orthopedics Ltd.

CarboClear® Lumbar Cage System

Applicant Name

CarboFix Orthopedics Ltd.
11 Ha'hoshlim St., Herzeliya 4672411, Israel

Contact Person

Hila Wachsler-Avrahami
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Date Prepared

December 3, 2019

Trade/Proprietary Name

CarboClear® Lumbar Cage System

Common Name

Intervertebral Body Fusion Device

Regulation Number and Device Class

21 CFR §888.3080; Class II

Product Code and Review Panel

MAX; Orthopedic

Predicate Devices

Primary Predicates

- CONCORDE® Bullet Lumbar Interbody System (DePuy Spine, Inc.; K151773, and more)

Additional Predicates

- FORZA® PTC Spacer System (Orthofix Inc.; K152475)
- icotec Interbody Cage System (icotec ag; K172480)

Reference Devices

With regards to the materials incorporated into the system components, comparison is also made to the following cleared products by the Company:

- CarboClear VBR System (CarboFix Orthopedics Ltd.; K192214)
- CarboClear Pedicle Screw System (CarboFix Orthopedics Ltd.; K173487, K182377)

Indications for Use

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Patients should have at least six months of non-operative treatment prior to surgery.

System Description

CarboClear® Lumbar Cage System is composed of implants of various sizes, and instruments.

The CarboClear® Lumbar Cage is made of carbon fiber-reinforced polyetheretherketone (CFR-PEEK), with titanium alloy endplates. It is implanted in the intervertebral disc space with bone graft and is designed to maintain disc height and to facilitate vertebral fusion. The CarboClear® Lumbar Cage System should be used with a supplemental fixation system.

Performance Data and Substantial Equivalence

The CarboClear® Lumbar Cage System intended use, design, dimensions, material, 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 tests according to ASTM F2077; static and dynamic compression-shear tests according to ASTM F2077; wear evaluation; subsidence test according to ASTM F2267; expulsion test; and endplate shear test according to ASTM F1044. Test results demonstrated that the device is substantially equivalent to the identified predicates.

In addition, bacterial endotoxin testing was conducted for the CarboClear® Lumbar Cage.

Conclusion

Based on the information provided in this Premarket Notification, the subject CarboClear® Lumbar Cage System is substantially equivalent to its predicate devices.