June 4, 2020

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

Re: K200883
Trade/Device Name: CarboClear® Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 30, 2020
Received: April 2, 2020

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

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K200883

Device Name
CarboClear® Cervical Plate System

Indications for Use *(Describe)*

CarboClear Cervical Plate System is intended for anterior fixation of the cervical spine.
The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spine fusion in patients with the following:
Degenerative disc disease (DDD) (as identified by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis and tumors, deformity (e.g., scoliosis, kyphosis, lordosis), pseudoarthrosis, failed previous fusions.

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® Cervical Plate 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**

March 2020

**Trade/Proprietary Name**

CarboClear® Cervical Plate System

**Common Name**

Appliance, Fixation, Spinal Intervertebral Body

**Classification Name**

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

**Predicate Devices**

Primary

- Spider® Cervical Plating System (X-spine Systems, Inc.; K170224, and more)

Additional

- Anterior CSLP System (Synthes; K030866, and more)
- Reflex® Hybrid Anterior Cervical Plate System (Stryker; K040261, and more)

Reference

- CarboClear Pedicle Screw System (CarboFix Orthopedics Ltd.; K173487, K182377)
- Piccolo Composite Plate System (CarboFix Orthopedics Ltd.; K102597, K120409, K130061, K182015, and more)

**Indications for Use**

CarboClear Cervical Plate System is intended for anterior fixation of the cervical spine.

The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spine fusion in patients with the following:

Degenerative disc disease (DDD) (as identified by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (*i.e.*, fractures or dislocations), spinal stenosis and tumors, deformity (*e.g.*, scoliosis, kyphosis, lordosis), pseudoarthrosis, failed previous fusions.

**System Description**

The CarboClear Cervical Plate System comprises implants (plates and screws) in different dimensions, and instruments.

The CarboClear cervical plates are made of carbon fiber reinforced polyetheretherketone (CFR-PEEK) and may incorporate tantalum markers. The screws are made of titanium alloy.

**Substantial Equivalence**

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

Performance characteristics, including static and dynamic compression bending, and static torsion, per ASTM F1717, and static screw pushout testing, are comparable to those of predicate devices (as applicable), thus demonstrating substantially equivalent mechanical performance of the subject device.

In addition, bacterial endotoxin evaluation was conducted for the system.