August 5, 2020

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

Re: K201251
Trade/Device Name: CarboClear Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 3, 2020
Received: May 11, 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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*

K201251

Device Name
CarboClear® Lumbar Cage System

Indications for Use *(Describe)*

CarboClear® Navigated Instruments are intended to be used during the preparation and placement of CarboClear® Pedicle Screws during spinal surgery to assist the surgeon in precisely locating anatomical structures. CarboClear® Navigated Instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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.

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510(k) Summary

CarboFix Orthopedics Ltd.

CarboClear® Navigated Instruments

Applicant Name

CarboFix Orthopedics, Ltd.

11 Ha'hoshlim St., Herzeliya 4672411, Israel

Contact Person

Hila Wachsler-Avrahami

CarboFix Orthopedics, Ltd.

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

Date Prepared

August 4, 2020

Trade/Proprietary Name

CarboClear® Navigated Instruments

Common Name

Stereotaxic Instrument; Navigated Probe, Navigated Bone Tap, Navigated Screwdriver

Regulation Number and Device Class

21 CFR §882.4560; Class II

Product Code, Regulation Description and Review Panel

OLO; Stereotaxic Instrument; Orthopedic

Predicate Devices

Primary Predicate:

- Medtronic Navigated Instruments (Medtronic Sofamor Danek; K153442)

Additional Predicates:

- Medtronic Navigated Instruments (Medtronic Sofamor Danek; K124004, K140454, K143375)
- Globus Navigation Instruments (Globus Medical, Inc.; K153203)
- CarboClear® Pedicle Screw System Instruments (CarboFix Orthopedics, Ltd.; K173487, K182377)

Indications for Use

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System Description

CarboClear® Navigated Instruments are reusable, manually operated, instruments, including probes, bone taps and a screwdriver. These instruments are intended to be used with the Medtronic StealthStation® Navigation System, to assist surgeons in precisely locating anatomical structures for preparation and placement of CarboClear Pedicle Screws during spinal surgery.

Technological Characteristics and Comparison to Predicates

CarboClear® Navigated Instruments, similar to the predicate navigated instruments, are intended to be used with the Medtronic's StealthStation® System to assist the surgeon in locating anatomical structures. Additionally, the CarboClear® Navigated Instruments and their predicate devices have similar technological characteristics, including design, dimensions, materials and technology, and they function in the same manner. Performance testing demonstrates that the CarboClear® Navigated Instruments are substantially equivalent to the predicate devices.

Performance Data

Design validation testing, including engineering analysis, compatibility testing and registration, was conducted to verify that the CarboClear® Navigation Instruments are appropriate for their intended use, to ensure functionality, accuracy and compatibility with the Medtronic StealthStation® System using the NavLock Tracker, and to demonstrate substantial equivalence to the predicate instruments.

Engineering analysis included comparative dimensional measurements for the subject and predicate instruments. Compatibility testing evaluated the physical compatibility and connection between the NavLock Tracker and CarboClear® Navigated Instruments. Registration testing was performed to ensure that the instruments can be registered to the StealthStation® System.

Substantial Equivalence

Based on the information provided in this Premarket Notification, CarboClear® Navigated Instruments have been found to be substantially equivalent to the predicate devices with respect to intended use, technological characteristics and performance.