July 3, 2023

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

Re: K231280
Trade/Device Name: CarboClear® X Pedicle Screw System; CarboClear® X Navigated Instruments; CarboClear® X Fenestrated Pedicle Screw System with High V+® Bone Cement
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, OLO, PML
Dated: May 2, 2023
Received: May 3, 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,

Colin O'neill -S

Colin O'Neill, M.B.E.
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)*
K231280

Device Name

CarboClear® X Pedicle Screw System

Indications for Use *(Describe)*

The CarboClear® X Pedicle Screw System is 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

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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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

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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)*
K231280

Device Name

CarboClear® X Navigated Instruments

Indications for Use *(Describe)*

CarboClear® X Navigated Instruments are intended to be used during the preparation and placement of CarboClear® X Pedicle Screws during spinal surgery to assist the surgeon in precisely locating anatomical structures. CarboClear® X 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)

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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K231280

Device Name
CarboClear® X Fenestrated Pedicle Screw System with High V+® Bone Cement

Indications for Use *(Describe)*
CarboClear® X Fenestrated Pedicle Screw System

When used in conjunction with High V+ ® Bone Cement, the CarboClear® X Fenestrated Pedicle Screw System is 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The CarboClear® X Fenestrated Pedicle Screw System augmented with High V+® Bone Cement is for use at spinal levels where the structural integrity of the spine is not severely compromised.

High V+® Bone Cement

When used in conjunction with the CarboClear® X Fenestrated Pedicle Screw System, High V+® Bone Cement is 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. High V+® Bone Cement is limited to use at spinal levels where the structural integrity of the spine is not severely compromised.

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)

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510(K) Summary

CarboFix Orthopedics Ltd.

CarboClear® X Pedicle Screw System, CarboClear® X Navigated Instruments, CarboClear® X Fenestrated Pedicle Screw System with High V+® Bone Cement - Minimally Invasive Surgery (MIS) Approach

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

May 2023

Trade/Proprietary Name

1. CarboClear® X Pedicle Screw System
2. CarboClear® X Navigated Instruments
3. CarboClear® X Fenestrated Pedicle Screw System (with High V+® Bone Cement)

Common Name

1. Pedicle Screw System
2. Stereotaxic Instrument

3. Polymethylmethacrylate (PMMA) Bone Cement

Regulation Number and Device Class

1. Class II; 21 CFR §888.3070
2. Class II; 21 CFR §882.4560
3. Class II; 21 CFR §888.3027

Product Code and Review Panel

1. NKB; Thoracolumbosacral Pedicle Screw System; Orthopedic
2. OLO; Stereotaxic Instrument; Orthopedic
3. PML; Bone Cement, Posterior Screw Augmentation

Predicate Devices

Primary

1. VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 (icotec AG; K193423)

Additional

1. VADER® Pedicle System, G21 Cement (icotec AG; K200596)
2. VIPER PRIME™ Screws / navigated inserter (Medos International SARL; K162912, K170937)
3. CarboClear X Pedicle Screw System, CarboClear X Navigated Instruments (CarboFix Orthopedics Ltd., K210716).
4. CarboClear Fenestrated Pedicle Screws, High V+ Bone Cement (CarboFix Orthopedics Ltd., K190526)

Indications for Use

CarboClear® X Pedicle Screw System

The CarboClear® X Pedicle Screw System is 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

CarboClear® X Navigated Instruments

CarboClear® X Navigated Instruments are intended to be used during the preparation and placement of CarboClear® X Pedicle Screws during spinal surgery to assist the surgeon in precisely locating anatomical structures. CarboClear® X 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.

CarboClear® X Fenestrated Pedicle Screw System

When used in conjunction with High V+® Bone Cement, the CarboClear® X Fenestrated Pedicle Screw System is 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The CarboClear® X Fenestrated Pedicle Screw System augmented with High V+® Bone Cement is for use at spinal levels where the structural integrity of the spine is not severely compromised.

High V+® Bone Cement

When used in conjunction with the CarboClear® X Fenestrated Pedicle Screw System, High V+® Bone Cement is 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. High V+® Bone Cement is limited to use at spinal levels where the structural integrity of the spine is not severely compromised.

System Description

CarboClear® X Pedicle Screw System

The CarboClear® X Pedicle Screw System is composed of implants in various dimensions, used to build a spinal construct; and of a set of instruments, intended to assist in the insertion and placement of the implants.

The implants for minimally invasive surgical procedures include pedicle screws, rods, and a set screw (locking element). They are made of carbon fiber-reinforced polyetheretherketone (CFR-PEEK). The threaded portion of the pedicle screws is encased within a thin titanium shell. Implants may include tantalum markers.

The implants are supplied sterile, and are intended for single use.

CarboClear® X Navigated Instruments

CarboClear® X Navigated Instruments are manually operated, instruments intended to be used with the Medtronic StealthStation® Navigation System, to assist surgeons in precisely locating anatomical structures for preparation and placement of CarboClear® X pedicle screws during spinal surgery.

CarboClear® X Fenestrated Screw System

The CarboClear® X Fenestrated Pedicle Screw System consists of cannulated polyaxial pedicle screws in various dimensions, with lateral fenestrations near the screws' distal tip, which allow controlled delivery of polymethylmethacrylate (PMMA) bone cement (High V+® Bone Cement) into the vertebral body. The Screws are implanted with the components of the CarboClear® X Pedicle Screw System.

The CarboClear® X Fenestrated Screw System is made of carbon fiber-reinforced polyetheretherketone (CFR-PEEK). The threaded portion of the screws is encased within a thin titanium shell, and includes a small tantalum marker.
The CarboClear® X Fenestrated Screw System is supplied sterile, and is intended for single use.

High V+® Bone Cement

Self-curing, high viscosity, radiopaque PMMA based bone cement. It is provided sterile in two components: 20 grams of powder and 8.6 grams of liquid. The powder component consists of polymethylmethacrylate, with barium sulfate and hydroxyapatite as radiopacifier, and benzoyl peroxide as an initiator. The liquid component comprises methylmethacrylate monomer, with N,N–dimethyl-p-toluidine as a promoter, and hydroquinone as a stabilizer. The powder and liquid components are mixed into homogenous paste, to initiate the polymerization reaction.

Purpose of Submission

Modification to the previously cleared CarboClear® X Pedicle Screw System and CarboClear® Navigated Instruments (K210716), as well as Fenestrated Screws with High V+® Bone Cement (K190526) to add the option of minimally invasive surgery approach.

Performance Data

Design validation evaluation, including engineering analyses and testing, was conducted to demonstrate that the CarboClear® X Pedicle Screw System is appropriate for its intended use, and is substantially equivalent to predicate devices, as applicable.

Substantial Equivalence

The CarboClear® X Pedicle Screw System and Navigated Instruments (including fenestrated screws), as intended for use in minimally invasive surgical approach, provide

for intended use, design, dimensions, materials, technological characteristics, and principles of operation which 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® X Pedicle Screw System, including fenestrated screws, and Navigated Instruments, as intended for use in minimally invasive surgical approach, are substantially equivalent to their predicate devices.