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

April 25, 2024

Re: K240846
Trade/Device Name: CarboClear® Hybrid Pedicle Screw System; CarboClear® Hybrid Navigated Instruments; CarboClear® Hybrid Fenestrated Pedicle Screw System and High V+® Bone Cement; CarboClear® X Fenestrated Pedicle Screw System and High V+® Bone Cement
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, PML, OLO
Dated: March 27, 2024
Received: March 27, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.04.25 13:25:22 -04'00'

for

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240846

Device Name

CarboClear® Hybrid Pedicle Screw System;
CarboClear® Hybrid Navigated Instruments;
CarboClear® Hybrid Fenestrated Pedicle Screw System and High V+® Bone Cement;
CarboClear® X Fenestrated Pedicle Screw System and High V+® Bone Cement

Indications for Use *(Describe)*

CarboClear® Hybrid Pedicle Screw System (Oncological)
The CarboClear® Hybrid 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® Hybrid Pedicle Screw System (DDD)
The CarboClear® Hybrid Pedicle Screw System is intended to provide rigid immobilization and stabilization of lumbar and/or sacral segments as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level from L2 to S1, with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have at least six months of non-operative treatment. The CarboClear® Hybrid Pedicle Screw System is intended to be used with an intervertebral body fusion device implanted at the same spinal level with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

CarboClear® Hybrid Navigated Instruments
CarboClear® Hybrid Navigated Instruments are intended to be used during the preparation and placement of CarboClear® Hybrid Pedicle Screws during spinal surgery to assist the surgeon in precisely locating anatomical structures. CarboClear® Hybrid 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® Hybrid Fenestrated Pedicle Screw System
When used in conjunction with High V+® Bone Cement, the CarboClear® Hybrid 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® Hybrid 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.

When used without cement, the CarboClear® Hybrid Fenestrated Pedicle Screws are intended:
(a) 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.
(b) to provide rigid immobilization and stabilization of lumbar and/or sacral segments as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level from L2 to S1, with up to

Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have at least six months of non-operative treatment. The CarboClear® Hybrid Pedicle Screw System is intended to be used with an intervertebral body fusion device implanted at the same spinal level with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

High V+® Bone Cement
When used in conjunction with the CarboClear® Hybrid 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.

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.

When used without cement, the CarboClear® X Fenestrated Pedicle Screw System is intended:
(a) 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.
(b) to provide rigid immobilization and stabilization of lumbar and/or sacral segments as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level from L2 to S1, with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have at least six months of non-operative treatment. The CarboClear® X Pedicle Screw System is intended to be used with an intervertebral body fusion device implanted at the same spinal level with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

CarboFix Orthopedics Ltd.

CarboClear® Hybrid Pedicle Screw System, CarboClear® Hybrid Navigated Instruments, CarboClear® Hybrid Fenestrated Pedicle Screw System and High V+® Bone Cement, CarboClear® X Fenestrated Pedicle Screw System and High V+® Bone Cement

APPLICANT NAME

CarboFix Orthopedics Ltd.
11 Ha'hoshlim St., Herzeliya 4672411, Israel
Tel: +972 9 9511511, Fax: +972 9 9548939

CONTACT PERSON

Hila Wachsler-Avrahami
CarboFix Orthopedics Ltd.
11 Ha'hoshlim St., Herzeliya 4672411, Israel
Tel: +972 9 9511511, Fax: +972 9 9548939

DATE PREPARED

March 27, 2024

TRADE/PROPRIETARY NAME

1. CarboClear® Hybrid Pedicle Screw System
2. CarboClear® Hybrid Navigated Instruments
3. CarboClear® Hybrid Fenestrated Pedicle Screw System and High V+ Bone Cement
4. CarboClear® X Fenestrated Pedicle Screw System and High V+ Bone Cement

COMMON NAME

1. Thoracolumbosacral 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, REGULATORY DESCRIPTION AND REVIEW PANEL

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

PREDICATE DEVICES

Primary Predicate Device:

CarboClear® X Pedicle Screw System (CarboFix Orthopedics Ltd.; K210716, K231280, K233944).

Additional Predicate Devices:

1. CarboClear® X Navigated Instruments (CarboFix Orthopedics Ltd.; K210716, K231280, K233944)
2. CarboClear® X Fenestrated Pedicle Screw System, High V+® Bone Cement (CarboFix Orthopedics Ltd.; K231280)
3. VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 (Icotec ag; K190545, K193423)
4. VADER® Pedicle System, G21 Cement (Icotec ag; K200596, K222789)
5. CD HORIZON® Spinal System (Medtronic Sofamor Danek; K082236 and more)
6. CD HORIZON™ Fenestrated Screw Set (Medtronic Sofamor Danek; K170347)
7. Medtronic Navigated Manual Reusable Instruments (Medtronic Sofamor Danek; K153442 and more)

INDICATIONS FOR USE

CarboClear® Hybrid Pedicle Screw System

CarboClear® Hybrid Pedicle Screw System (Oncology)

The CarboClear® Hybrid 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® Hybrid Pedicle Screw System (DDD)

The CarboClear® Hybrid Pedicle Screw System is intended to provide rigid immobilization and stabilization of lumbar and/or sacral segments as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level from L2 to S1, with up to Grade I

spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have at least six months of non-operative treatment.

The CarboClear® Hybrid Pedicle Screw System is intended to be used with an intervertebral body fusion device implanted at the same spinal level with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

CarboClear® Hybrid Navigated Instruments

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

When used in conjunction with High V+® Bone Cement, the CarboClear® Hybrid 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® Hybrid 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.

When used without cement, the CarboClear® Hybrid Fenestrated Pedicle Screws are intended:

(a) 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.

(b) to provide rigid immobilization and stabilization of lumbar and/or sacral segments as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level from L2 to S1, with up to Grade I spondylolisthesis. DDD is defined as back pain of

discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have at least six months of non-operative treatment.

The CarboClear® Hybrid Pedicle Screw System is intended to be used with an intervertebral body fusion device implanted at the same spinal level with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

High V+® Bone Cement

When used in conjunction with the CarboClear® Hybrid 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.

CarboClear® X Pedicle Screw System

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.

When used without cement, the CarboClear® X Fenestrated Pedicle Screws are intended:

(a) 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.

(b) to provide rigid immobilization and stabilization of lumbar and/or sacral segments as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level from L2 to S1, with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and

radiographic studies. Patients should be skeletally mature and have at least six months of non-operative treatment.

The CarboClear® X Pedicle Screw System is intended to be used with an intervertebral body fusion device implanted at the same spinal level with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

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

The ***CarboClear® Hybrid 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 CarboClear® Hybrid Pedicle Screws, including CarboClear® Hybrid Fenestrated Screws, are made of carbon fiber-reinforced polyetheretherketone (CFR-PEEK), with titanium alloy tulip. Their threaded portion is encased within a thin titanium shell. They are used with a compatible titanium alloy locking element, and with CarboClear X CFR-PEEK rods and trans-connectors. The implants may include tantalum markers. CarboClear X titanium alloy rod is also offered.

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

The CarboClear® Hybrid implants may be implanted in an open approach or using a minimally invasive surgery (MIS) approach.

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

The ***CarboClear® Hybrid Fenestrated Pedicle Screws*** and ***CarboClear® X Fenestrated Pedicle Screws*** are cannulated polyaxial pedicle screws in various dimensions, with lateral fenestrations near screws' distal tip, which allow controlled delivery of polymethylmethacrylate (PMMA) bone cement (High V+® Bone Cement) into the vertebral body in oncological patients.
These implants may also serve as traditional cannulated pedicle screws when used without bone cement.

The ***High V+ Bone Cement*** is a 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 (K210716, K231280, K233944).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

- The CarboClear® Hybrid Pedicle Screw System differs from the primary predicate in the screw tulip and locking element material.
- The CarboClear® Hybrid pedicle screws are used with rods identical to the rods of the primary predicate.
- The subject CarboClear® X fenestrated screws and CarboClear® Hybrid fenestrated screws have the same indications as CarboFix fenestrated screws previously cleared in K190526 and K231280, when augmented with cement (High V+® Bone Cement). The subject fenestrated screws may also be used without cement, for the non-cement augmented indications stated in the Indications for Use section.

PERFORMANCE DATA

Performance characteristics included static and dynamic compression bending tests according to ASTM F1717, as well as static flexion-extension test, axial gripping capacity test, and torsional gripping capacity test according to ASTM F1798. The results of the tests

are comparable to those of the predicate devices, demonstrating substantially equivalent performance of the subject and predicate devices.

SUBSTANTIAL EQUIVALENCE

The intended use, design, dimensions, materials, technological characteristics, principles of operation, and performance of the CarboClear® Hybrid Pedicle Screw System (including the CarboClear® Hybrid Navigated Instruments and the CarboClear® Hybrid Fenestrated Pedicle Screw System (with High V+® Bone Cement)), and the CarboClear X Fenestrated Pedicle Screw System, are substantially equivalent to those of the predicate devices.

CONCLUSION

Based on the information provided in this 510(k) Premarket Notification, the CarboClear® Hybrid Pedicle Screw System, including the CarboClear® Hybrid Navigated Instruments and the CarboClear Hybrid Fenestrated Pedicle Screw System (with High V+® Bone Cement); and the CarboClear X Fenestrated Pedicle Screw System, are substantially equivalent to their predicate devices.