September 19, 2019

CarboFix Orthopedics Ltd.
Ms. Hila Wachsler-Avrahami
Regulatory Affairs
11 Ha'hoshlim Street
Herzeliya, 4672411
ISRAEL

Re: K190526
Trade/Device Name: High V+ Bone Cement , CarboClear® Fenestrated Pedicle Screws
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: PML, NKB
Dated: August 6, 2019
Received: August 12, 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,

Ronald P. Jean, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190526

Device Name
High V+ Bone Cement

Indications for Use *(Describe)*
When used in conjunction with the CarboClear Fenestrated Pedicle Screws, 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.

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.

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K190526

Device Name
CarboClear® Fenestrated Pedicle Screws

Indications for Use *(Describe)*
When used in conjunction with High V+ Bone Cement, the CarboClear Fenestrated Pedicle Screws are 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 Fenestrated Pedicle Screws augmented with High V+ Bone Cement are for 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.

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510(K) Summary

CarboFix Orthopedics Ltd.

CarboClear® Fenestrated Pedicle Screws 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

Date Prepared

February 28, 2019

Device Regulation and Classification

Trade / Proprietary Name	High V+ Bone Cement	CarboClear® Fenestrated Pedicle Screws
Common Name	Polymethylmethacrylate (PMMA) Bone Cement	Pedicle Screw System
Device Classification	Class II	Class II
Product Code	PML	NKB
Regulation Description	Bone Cement, Posterior Screw Augmentation	Thoracolumbosacral Pedicle Screw System
Regulation Number	21 CFR §888.3027	21 CFR §888.3070
Panel	Orthopaedic	Orthopaedic

Predicate Devices

The subject High V+ Bone Cement is substantially equivalent to the primary predicate device - High V+ (Teknimed® SAS; K161114); and to the additional predicate device - High V+ Bone Cement (NuVasive, Incorporated; K180498).

The subject CarboClear Fenestrated Pedicle Screws are substantially equivalent to the predicate device - CarboClear® Pedicle Screws (CarboFix Orthopedics Ltd.; K173487, K182377); and to the additional predicate devices - NuVasive® Reline® Fenestrated Screws (NuVasive, Incorporated; K180498).

Indications for Use

High V+ Bone Cement:

When used in conjunction with the CarboClear Fenestrated Pedicle Screws, 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 Fenestrated Pedicle Screws:

When used in conjunction with High V+ Bone Cement, the CarboClear Fenestrated Pedicle Screws are 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 Fenestrated Pedicle Screws augmented with High V+ Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

System Description

The ***CarboClear 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. The CarboClear Fenestrated Screws are implanted with components of the CarboClear Pedicle Screw System.

The CarboClear Fenestrated Screws are 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 Fenestrated Screws are supplied sterile, and are intended for single use.

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.

Summary Comparison of Technological Characteristics and Intended Use with Predicate Devices

The subject ***CarboClear Fenestrated Pedicle Screws*** are similar to the cleared CarboClear Pedicle Screws (K173487, K182377) in their material, design, dimensions, production processes and sterilization, and additionally include lateral fenestrations at their distal portion. Furthermore, the CarboClear Fenestrated Pedicle Screws are implanted with the components of the cleared CarboClear Pedicle Screw System. The CarboClear Fenestrated Pedicle Screws are intended for the treatment of the same population as the cleared CarboClear Pedicle Screws, however their fixation is further augmented with bone cement.

In addition, the intended use, design, dimensions and principles of operation of the CarboClear Fenestrated Pedicle Screws are substantially equivalent to those of the additional predicate devices.

The subject ***High V+ Bone Cement*** is identical in composition, production processes including sterilization, and its manufacturer to the primary predicate device - the High V+ bone cement (Teknimed, K161114; and NuVasive, K180498). Its delivery method (via fenestrated screws) and indications for use (patients with advanced stage spinal tumors and short life expectancy) are also similar to those of the High V+ Bone Cement (NuVasive, K180498).

Additionally, the indications for use, cement composition and principles of operation of the subject High V+ Bone Cement are substantially equivalent to those of the additional predicate devices.

Performance Data

Comparative bench testing was provided to support substantial equivalence of the subject devices and their predicate devices. Mechanical testing included axial pullout strength test according to ASTM F2193 and ASTM F543, insertion and removal torque tests, and static bending and torsion tests. In addition, compatibility and

performance test was conducted for CarboClear fenestrated screws and High V+ Bone Cement, to verify proper operation of the components and to characterize cement flow and bolus formation.

Conclusion

Based on the information provided in this Premarket Notification, the subject CarboClear Fenestrated Pedicle Screws and High V+ Bone Cement are substantially equivalent to their legally marketed predicate devices.