



July 18, 2018

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

Re: K173487

Trade/Device Name: CarboClear[®] Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: June 19, 2018
Received: June 21, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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 -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173487

Device Name

CarboClear® Pedicle Screw System

Indications for Use (Describe)

The CarboClear 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.

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510(K) Summary

CarboFix Orthopedics Ltd.

CarboClear[®] Pedicle Screw System (Oncology)

Applicant Name

CarboFix Orthopedics, Ltd.

11 Ha'hoshlim St., Herzeliya 4672411, Israel

Contact Person

Hila Wachsler-Avrahami

CarboFix Orthopedics, Ltd.

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Date Prepared

July 18, 2018

Trade/Proprietary Name

CarboClear[®] Pedicle Screw System

Common Name

Pedicle Screw System

Regulatory Classification Name and Number, and Product Code

Thoracolumbosacral pedicle screw system; 21 CFR §888.3070; Class II;

Product Code NKB.

Predicate Devices

Primary Predicate:

- Mesa Spinal System (K2M, Inc.; K052398 and more)

Additional Predicates:

- CD HORIZON[®] Fenestrated Screw Set (Medtronic Sofamor Danek; K152604, K170347)
- VIPER[®] and EXPEDIUM[®] Fenestrated Screw Systems (DePuy Spine, Inc.; K160879, K170543)

Indications for Use

The CarboClear 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.

System Description

The CarboClear 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 implants include pedicle screws, rods and locking elements. The implants are made of carbon fiber-reinforced polyetheretherketone (CFR-PEEK). The threaded portion of the pedicle screws is encased within a thin titanium shell.

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

Performance Data and Substantial Equivalence

The CarboClear Pedicle Screw System intended use, design, technological characteristics, and principles of operation are substantially equivalent to those of the predicate devices, as applicable. The material is different but does not raise any different safety and effectiveness questions.

Performance characteristics included static and dynamic tests according to ASTM F 1717, and tests according to ASTM F 1798, ASTM F 2193, ASTM F 543; as well as fatigue lateral bending-axial rotation test and rod creep test. The test results are comparable to those of predicate devices, as applicable, demonstrating that the device

is safe and effective for its intended use.

Clinical data for the CarboClear System was presented for the target population specified in the indications for use statement, and supports the safety and effectiveness of the device.

Conclusion

Based on the information provided in this Premarket Notification, including clinical and non-clinical performance data, the subject CarboClear[®] Pedicle screw System is substantially equivalent to its predicate devices.