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

October 11, 2018

Re: K182015
Trade/Device Name: Piccolo Composite® Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: July 24, 2018
Received: July 27, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Jesse Muir -S
2018.10.11 19:07:40
-04'00'

For:
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K182015

Device Name
Piccolo Composite® Plate System

Indications for Use *(Describe)*

Piccolo Composite Lapidus Plate System:

The Piccolo Composite foot and ankle plates are indicated for fixation of osteotomies, fusions, fractures, nonunions, malunions and replantations of small bones and small bone fragments in adult and adolescent (12 - 21 years) patients, including the foot and ankle, and including in osteopenic bone.

The Lapidus plates are indicated for fusion and arthrodesis of the 1st tarsometatarsal joint (Lapidus Fusions).

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.

Piccolo Composite® Lapidus Plate System

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

July 2018

Trade/Proprietary Name

Piccolo Composite® Plate System

Common Name

Bone Plating System

Classification Name

Single/multiple component metallic bone fixation appliances and accessories; (21 CFR §888.3030; Class II; Product Code HRS).

Predicate Devices

Primary

- Piccolo Composite® Plate System (CarboFix Orthopedics Ltd.; K102597, K120409, K130061, K143496, K160002, K170401)

Additional

- ORTHOLOC® 3Di Foot Plating Reconstruction System (Wright Medical Technology, Inc.; K152974, and more)
- 2.4mm/2.7mm Variable Angle LCP Forefoot/Midfoot System – First TMT Fusion Plates (Synthes; K100776)

Indications for Use

The Piccolo Composite foot and ankle plates are indicated for fixation of osteotomies, fusions, fractures, nonunions, malunions and replantations of small bones and small bone fragments in adult and adolescent (12 - 21 years) patients, including the foot and ankle, and including in osteopenic bone.

The Lapidus plates are indicated for fusion and arthrodesis of the 1st tarsometatarsal joint (Lapidus Fusions).

System Description

The Piccolo Composite Lapidus Plate System comprises implants (plates and screws), and a set of instruments.

The plates are made of carbon fiber reinforced polyetheretherketone (CFR-PEEK), and are marked with a tantalum thread, to provide for their visualization under fluoroscopy.

The screws are made of titanium alloy. Both non-locking and locking 2.7mm screws are available, in various lengths. Cannulated Lag Screws are also provided.

Substantial Equivalence

The Piccolo Composite Lapidus Plate System intended use, design, materials, technological characteristics, and principles of operation are substantially equivalent to those of the predicate devices, as applicable.

Performance characteristics included static and dynamic bending (evaluated per ASTM F 382) and are comparable to those of predicate devices (as applicable), thus demonstrating that the device is safe and effective for its intended use.

In addition, bacterial endotoxin testing was conducted for the Piccolo Composite Plate System.