October 8, 2020

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

Re: K201917
Trade/Device Name: Piccolo Composite Proximal Tibia 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 8, 2020
Received: July 10, 2020

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,

for - Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative 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)*
K201917

Device Name
Piccolo Composite® Proximal Tibia Plate System

Indications for Use *(Describe)*

The Piccolo Composite Proximal Tibia Plate System is intended to treat fractures of the proximal tibia in adults and adolescents in which the growth plates have fused.
For Lateral Plates – non-unions, malunions, and factures including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures.
For Medial Plates – intended to buttress metaphyseal fractures of the medial tibia plateau, split-type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. The plates may also be used for fixation of the proximal quarter (lateral and medial) of the tibia as well as segmental fractures of the proximal tibia.

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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K201917

510(K) Summary

CarboFix Orthopedics Ltd.

Piccolo Composite® Proximal Tibia 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

September 2020

Trade/Proprietary Name

Piccolo Composite® Proximal Tibia 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

- 3.5mm LCP / VA-LCP Proximal Tibia Plate System (DePuy Synthes, Inc.; K120689)

Additional

- 3.5mm LCP / VA-LCP Proximal Tibia Plate System (DePuy Synthes, Inc.; K030597, K032269, K050646, and more)
- A.L.P.S Proximal Tibial Plating System (Biomet; K090877)
- Piccolo Composite Plate System (CarboFix Orthopedics Ltd.; K102597, K120409, K130061, K182015, and more)

Indications for Use

The Piccolo Composite Proximal Tibia Plate System is intended to treat fractures of the proximal tibia in adults and adolescents in which the growth plates have fused.

For Lateral Plates – non-unions, malunions, and factures including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures.

For Medial Plates – intended to buttress metaphyseal fractures of the medial tibia plateau, split-type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. The plates may also be used for fixation of the proximal quarter (lateral and medial) of the tibia as well as segmental fractures of the proximal tibia.

System Description

The Piccolo Composite Proximal Tibia Plate System comprises implants (pre-contoured lateral and medial plates (in left and right configurations), and screws) in different dimensions, and instruments.

The Piccolo Composite proximal tibia plates are made of carbon fiber reinforced polyetheretherketone (CFR-PEEK) and incorporate tantalum markers. The screws are made of titanium alloy.

Performance Testing

Performance characteristics, including plate static and dynamic bending testing (evaluated per ASTM F 382), screw pushout testing from the plate, and screws performance evaluation (including insertion torque, pull out force and dimensional equivalence) are comparable to those of predicate devices (as applicable), thus demonstrating substantially equivalent mechanical performance of the subject device.

Substantial Equivalence

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