DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

CarboFix Orthopedics Ltd.
Ms. Yael Rubin
Director of Regulatory Affairs
11 Ha'hoshlim Street
Herzeliya, 4672411
ISRAEL

March 9, 2016

Re: K160002
Trade/Device Name: Piccolo Composite® Distal Volar Radius 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, KTT
Dated: February 4, 2016
Received: February 8, 2016

Dear Ms. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160002

Device Name
Piccolo Composite® Distal Volar Radius Plate System

Indications for Use *(Describe)*

The Piccolo Composite Distal Volar Radius Plate System is indicated for fractures and osteotomies of the distal volar radius.

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."

510(K) Summary

CarboFix Orthopedics Ltd.

Piccolo Composite® Distal Volar Radius 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., Herzliya 4672411, Israel
Tel: +972 9 9511511, Fax: +972 9 9548939

Date Prepared

February 3, 2016

Trade/Proprietary Name

Piccolo Composite® Distal Volar Radius Plate System

Common Name

Bone Plating System

Classification Name

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

Predicate Devices

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

- Synthes 2.4mm VA-LCP Two Column Volar Distal Radius Plate (Synthes; K083694)

Intended Use/Indications for Use

The Piccolo Composite Distal Volar Radius Plate System is indicated for fractures and osteotomies of the distal volar radius.

System Description

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

The "triangular" plates, added in this 510(k) Notification, are made of carbon fiber reinforced polyetheretherketone (CFR-PEEK), and are marked with a tantalum thread, to provide for their visualization under fluoroscopy, like the rest of the Piccolo Composite plates.

The "triangular" Piccolo Composite distal volar radius plate is 2.4mm thick. The plate shaft comprises 3 - 5 holes, corresponding to plate lengths in the range of 54 - 72 mm.

The screws and pegs are made of titanium alloy. Various screw types are available, such as cortical screws and locking screws, as well as pegs, in various dimensions.

Substantial Equivalence

The Piccolo Composite Distal Volar Radius 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 for the Piccolo Composite Distal Volar Radius Plate System components included bending of construct, 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.