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

December 28, 2017

Re: K173652
Trade/Device Name: Piccolo Composite® Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 26, 2017
Received: November 28, 2017

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. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173652

Device Name

Piccolo Composite® Nailing System

Indications for Use *(Describe)*

Piccolo Composite Proximal Femur Nails

The Piccolo Composite Proximal Femur Nails are indicated for the treatment of stable and unstable proximal femur fractures (pertrochanteric, intertrochanteric, high subtrochanteric fractures, and combinations of these fractures), including, fractures resulting from trauma, nonunions, malunions, pathological fractures, impending pathological fractures, tumor resections, and revision procedures.

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® Proximal Femur Nailing 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

December 2017

Trade/Proprietary Name

Piccolo Composite® Nailing System

Common Name

Intramedullary Nailing System

Classification Name

Rod, Fixation, Intramedullary and Accessories (21 CFR §888.3020; Product Code HSB).

Predicate Devices

Primary Predicate:

- Piccolo Composite® Proximal Femur Nailing System (CarboFix Orthopedics Ltd.; K153536, K151010)

Additional Predicate:

- Gamma3® Nail System (Stryker (Howmedica Osteonics Corp.); K043431 and more)

Intended Use/Indications for Use

The Piccolo Composite Proximal Femur Nails are indicated for the treatment of stable and unstable proximal femur fractures (pertrochanteric, intertrochanteric, high subtrochanteric fractures, and combinations of these fractures), including, fractures resulting from trauma, nonunions, malunions, pathological fractures, impending pathological fractures, tumor resections, and revision procedures.

System Description

The Piccolo Composite Nailing System includes nails, screws and a set of instruments.
The Piccolo Composite nail indicated for treatment of the proximal femur is a cylindrical rod. Nail mid-shaft diameter is 11mm, with the proximal end diameter of up to 17mm. Nail lengths are 180mm, 200mm, and in the range of 300 – 460mm. The nail provides for holes at the proximal and distal sections, designed for the insertion of a lag screw and interlocking screws. The lag screw is of 10.4mm diameter, with its length being in the range of 80mm to 110mm. The nails (and, optionally, the lag screws) are made of carbon fiber reinforced polymer and incorporate small amount of titanium/titanium alloy. Tantalum markers are embedded within the carbon fiber reinforced polymer, where applicable, to enable visualization during imaging. The distal screws, and, optionally, the lag screws, are made of titanium alloy.

Substantial Equivalence

The Piccolo Composite Proximal Femur Nailing 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 Proximal Femur Nailing System components included static and dynamic bending of implants construct, 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.