



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

January 6, 2016

CarboFix Orthopedics, Limited  
Yael Rubin  
Director of Regulatory Affairs  
11 Ha'hoshlim St.  
Herzeliya, 4627411  
ISRAEL

Re: K153536

Trade/Device Name: Piccolo Composite<sup>®</sup> Nailing System  
Regulation Number: 21 CFR 888.3020  
Regulation Name: Intramedullary fixation rod  
Regulatory Class: Class II  
Product Code: HSB  
Dated: December 8, 2015  
Received: December 10, 2015

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 Parts 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" (21CFR 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,

**Lori A. Wiggins -S**

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

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)

K153536

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.

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  
PRASStaff@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."*

**CarboFix Orthopedics Ltd.**  
Piccolo Composite® Nailing System – Proximal Femur

---

## **510(K) Summary**

**CarboFix Orthopedics Ltd.**  
**Piccolo Composite® Nailing System – Proximal Femur**

### **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**

December 2015

### **Trade/Proprietary Name**

Piccolo Composite® Nailing System

### **Common Name**

Intramedullary Nailing System

### **Classification Name**

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

---

### **Predicate Devices**

- Piccolo Composite® Nailing System (CarboFix Orthopedics Ltd.; K151010, K102369, K111056)
- Gamma3® Nail System (Stryker (Howmedica Osteonics Corp.); K043431 and more)

### **Intended Use/Indications for Use**

#### 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.

### **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 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 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.

---

**CarboFix Orthopedics Ltd.**

Piccolo Composite® Nailing System – Proximal Femur

---

Performance characteristics for the Piccolo Composite Proximal Femur Nailing System components included static and dynamic bending of construct, and lag screw torque to failure, and are comparable to those of predicate devices (as applicable), thus demonstrating that the device is safe and effective for its intended use.

---