DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 27, 2016

The Progressive Orthopaedic Company, LLC
Mr. Thomas Smith
Quality/Regulatory Consultant
801 US Highway 1, Suite B
North Palm Beach, Florida 33408

Re: K151424
Trade/Device Name: The Progressive Orthopaedic Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO
Dated: June 24, 2016
Received: June 27, 2016

Dear Mr. Smith:

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

Indications for Use

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

510(k) Number *(if known)*

K151424

Device Name

The Progressive Orthopaedic Total Hip System

Indications for Use *(Describe)*

The Progressive Orthopaedic Total Hip System implant components are indicated for use in cementless reconstruction of the articulating surface of femoral and acetabular portions of the hip that are severely disabled and/or very painful as a result of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis or traumatic arthritis
- Correction of functional deformity
- Non-union femoral neck fracture
- Trochanteric fractures of the proximal femur with head involvement which is unmanageable using other techniques.

The components can be used for primary hip arthroplasty or for revision of a failed total hip arthroplasty.

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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The PROGRESSIVE Orthopaedic Company

510(k) Summary

Applicant/Sponsor:	**The Progressive Orthopaedic Company, LLC.** **801 US Highway 1, Suite B** **North Palm Beach, FL, 33408** **(561) 440-4460**
Contact Person:	**Thomas Smith** **Quality and Regulatory Consulting** **801 US Highway 1, Suite B** **North Palm Beach, FL, 33408** **(203) 641-3936**
Proposed Trade Name:	**The Progressive Orthopaedic Total Hip System**
Common Name:	**Hip Joint Prosthesis**
Classification Name:	**Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358. This falls under the Orthopedics panel/87 as a Class II device.**
Device Product Code:	**LPH, LZO**
Predicate Devices:	**Progressive Orthopaedic Total Hip System (K143314)** **NovoSource NovoHip Total Hip System (K140701)**

Device Description:

The present 510k The Progressive Orthopaedic additional screw sizes and apical hole plug are components to be used with the Progressive Orthopaedic Total Hip System, previously cleared via K143314.

Screw Sizes	6.5mm OD x 15-45mm Length
Material	Ti6Al4V per ASTM 1472
Apical Hole Plug OD	∅ 8.52mm OD
Apical Hole Plug Thread	5/16 X 24 UNF 2A
Material	Ti6Al4V

The PROGRESSIVE Orthopaedic Company

Intended Use:

Hip joint arthroplasty

Indications for Use:

The Progressive Orthopaedic Total Hip System implant components are indicated for use in cementless reconstruction of the articulating surface of femoral and acetabular portions of the hip that are severely disabled and/or very painful as a result of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis or traumatic arthritis
- Correction of functional deformity
- Non-union femoral neck fracture
- Trochanteric fractures of the proximal femur with head involvement which is unmanageable using other techniques.

The components can be used for primary hip arthroplasty or for revision of a failed total hip arthroplasty.

Substantial Equivalence

The Progressive Orthopaedic Total Hip System and NovoSource Total Hip System have similar intended use, indications for use and the same manufacturing materials as the predicate device. The range of sizes of the Progressive Ortho Total Hip System is similar to the predicate devices.

Non-Clinical Testing

Mechanical testing has demonstrated the device's ability to perform under expected conditions. Testing included mechanical characterization testing, torsion, driving torque and pull out. In all testing, the subject device shows equivalent properties when compared to predicate products.

Testing has determined that the device is substantially equivalent to the predicate device in material, construction, and performance characteristics.

Clinical Performance Data Summary

No clinical testing was required.

The Progressive Orthopaedic Company 801 US Highway 1, Suite B, North Palm Beach, FL, 33408
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