



March 18, 2019

The Progressive Orthopaedic Company, LLC.
Brad Harris
CEO
10190 Riverside Drive, Suite 102
Palm Beach Gardens, Florida 33410

Re: K183344

Trade/Device Name: The Progressive Orthopaedic Company Total Knee System II
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented
Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: February 8, 2019
Received: February 14, 2019

Dear Brad Harris:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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,

Peter G.
Allen -S

Digitally signed by
Peter G. Allen -S
Date: 2019.03.18
20:47:35 -04'00'

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: 06/30/2020

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K183344

Device Name

The Progressive Orthopaedic Company Total Knee System II

Indications for Use (Describe)

The Progressive Orthopaedic Company Total Knee System II is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. The Progressive Orthopaedic Company Total Knee System II may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. The Progressive Orthopaedic Company Total Knee System II is designed for cemented use only.

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.

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The Progressive Orthopaedic Company Total Knee System II

6. 510(k) Summary

The following 510(k) Summary is provided in accordance with 21 CFR 807.92.

6.1 510(k) Owner and Registration

Owner's Name:	The Progressive Orthopaedic Company, LLC.
Address:	10190 Riverside Drive, Palm Beach Gardens, FL 33410
Phone Number:	(561) 440-4460
Fax Number:	(877) 299-6013
Date Summary Prepared:	November 30, 2018
Establishment Registration Number:	N/A

6.2 510(k) Contact

Contact:	Brad Harris
Address:	10190 Riverside Drive, Palm Beach Gardens, FL 33410
Phone Number:	(561) 602-3596
Fax Number:	(877) 299-6013
Contact Person:	Brad Harris

6.3 Device Name and Classification

Device Trade Name:	The Progressive Orthopaedic Company Total Knee System II
Device Common Name:	Total Knee Replacement
Regulation Number and Description:	21 CFR 888.3560
Device Class:	Class II
Product Codes:	JWH
Advisory Panel:	87 (Orthopedic)

6.4 Legally Marketed Predicate

The Progressive Orthopaedic Company Total Knee System II is utilizing the Progressive Orthopaedic Total Knee System as the predicate device (K142649/K150783). The Progressive Orthopaedic Company Total Knee System II features component designs, materials, indications, and manufacturing methods that are identical to the Progressive Orthopaedic Total Knee System.

The Progressive Orthopaedic Company Total Knee System II

6.5 Device Description

The Progressive Orthopaedic Company Total Knee System II is a fixed bearing implant available in posterior-stabilized (PS) and cruciate-retaining (CR) configurations. It is a patellofemorotibial, polymer/metal/polymer, semi-constrained, cemented knee prosthesis that consists of a femoral component, tibial insert, tibial tray and patellar component. The PS version has tibial inserts with posts and femoral components with cams that interact with the posts to help stabilize the knee after the posterior cruciate ligament is removed. The CR version of The Progressive Orthopaedic Company Total Knee System II has tibial inserts and femoral components without posts or cams, allowing the posterior cruciate ligament to be "retained" and provide stability to the knee joint. The femoral component articulates with the tibial insert component. The underside of the tibial insert component is flat and "snaps" into the tibial baseplate component. The design and sizing of the femoral components correspond to the natural femoral anatomy, enhancing stress distribution and restoring original femoral dimensions and normal rotation, extension and flexion. Each femoral component has the same intercondylar distance and radius of curvature. Each tibial insert component is complementarily shaped to conform to the femoral components. This allows any size femoral component to be matched with any size tibial component. The dome shape of each UHMWPE patellar component provides excellent contact with the femoral component and evenly distributes stresses. The dome shape of each patellar component also simplifies implantation by eliminating the need for rotational orientation.

6.6 Intended Use

The Progressive Orthopaedic Company Total Knee System II is identical to the predicate Progressive Orthopaedic Total Knee System. The indications for use are also identical.

The Progressive Orthopaedic Company Total Knee System II is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities.

The Progressive Orthopaedic Company Total Knee System II may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. The Progressive Orthopaedic Company Total Knee System II is designed for cemented use only.

6.7 Summary of Technological Characteristics

The Progressive Orthopaedic Company Total Knee System II is identical to the predicate Progressive Orthopaedic Total Knee System. Both devices are manufactured from identical materials, possess the same sizes, and feature the same packaging and sterilization processes. Extensive preclinical testing was performed on the predicate devices per K142649 and K150783 and found substantially equivalent. The performance tests are listed below and used herein to establish substantial equivalence (Section 19 Performance Testing – Bench)

Given that the subject device is identical to the predicate, the subject system is substantially equivalent to the predicate systems (K142649/K150783).

6.8 Performance Testing

Extensive preclinical performance testing was conducted and substantial equivalence determined per K142649 and K150783. The components of the subject device are identical to the predicate device, and therefore the

The Progressive Orthopaedic Company Total Knee System II

predicate device testing demonstrates substantial equivalence for the subject device. The results confirm that all components of The Progressive Orthopaedic Company Total Knee System II exhibit the appropriate mechanical characteristics for total knee joint replacement, and are substantially equivalent to the predicate devices.

- Fatigue performance of the tibial tray
- Interlock mechanism strength of the tibial tray and insert
- Shear fatigue strength of the tibial insert post
- Tibiofemoral contact area and stress
- Tibiofemoral constraint
- Patellofemoral constraint
- Range of motion

6.9 Conclusions

The Progressive Orthopaedic Company Total Knee System II is identical to the predicate Progressive Orthopaedic Total Knee System. The subject device has the same design features, materials, and indications for use as the predicate devices. The testing performed for the predicate device indicates that The Progressive Orthopaedic Company Total Knee System II is safe for clinical use.

The Progressive Orthopaedic Company Total Knee System II is substantially equivalent to the predicate device.