August 16, 2021

CPM Medical Consultants, LLC.
Andy Rynearson
Director of Engineering
1565 N. Central Expressway
Richardson, Texas 75080

Re: K210695
Trade/Device Name: CPM Medical Consultants Tibial Revision Knee System
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: May 14, 2021
Received: May 18, 2021

Dear Andy Rynearson:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K210695

Device Name
CPM Medical Device Consultants Revision Tibial Knee System

Indications for Use *(Describe)*

The CPM Medical Consultants Tibial Revision Knee System 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 device is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require constrained stabilization for tibiofemoral joint due to soft tissue in-balance. The tibial augments are to be attached to their respective components with a fixation screw or screws.

The CPM Medical Consultants Tibial Revision Knee System 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 CPM Medical Consultants Tibial Revision Knee System is designed for cemented use only.

The CPM Medical Consultants Tibial Revision Knee System is to be used in conjunction with the Progressive Orthopaedic Company Total Knee System cleared via K142649 & K150783. See below for a compatibility chart between systems.

Compatibility Chart

		CPM Medical Consultants Tibial Revision Components			
		PS+ Tibial Insert	Tibial Stem	Tibial Augments	Revision Tibial Tray
Progressive Orthopaedic Company Components	CR Femoral				
	PS Femoral				
	CR Tibial Insert				
	PS Tibial Insert				
	Tibial Tray				
	Patella				

Compatible Non-Compatible

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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CPM Medical Consultants Tibial Revision Knee System

510(k) Summary

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

510(k) Owner and Registration

Owner's Name:	CPM Medical Consultants, LLC.
Address:	1565 N. Central Expressway, Suite 200, Richardson, TX 75080
Phone Number:	(321) 316-2601
Fax Number:	N/A
Date Summary Prepared:	April 30, 2021
Establishment Registration Number:	N/A

510(k) Contact

Contact:	Andy Rynearson
Address:	1565 N. Central Expressway, Suite 200, Richardson, TX 75080
Phone Number:	(321) 316-2601
Fax Number:	N/A
Contact Person:	Andy Rynearson

Device Name and Classification

Device Trade Name:	CPM Medical Consultants Revision Tibial Knee System
Device Common Name:	Revision Tibial Knee Replacement
Regulation Number and Description:	21 CFR 888.3560
Device Class:	Class II
Product Codes:	JWH
Advisory Panel:	87 (Orthopedic)

Legally Marketed Predicate

CPM Medical Consultants is utilizing the Modal Manufacturing Total Knee System, previously cleared as the Progressive Orthopaedic Company Total Knee System (K142649/K150783), and the United Orthopedic Corporation U2 Total Knee System as the predicate devices (K082424/K122183). The CPM Medical Consultants Tibial Revision Knee System features component designs, materials, indications, and manufacturing methods that are similiar to the Modal Manufacturing Total Knee System and the United Orthopedic Corporation U2 Total Knee System. The CPM Medical Consultants Revision Tibial Knee System is to be used in conjunction with the previously cleared Progressive Orthopaedics/Modal Manufacturing Total Knee System (K142649/K150783).

CPM Medical Consultants Tibial Revision Knee System

Device Description

The CPM Medical Consultants Tibial Revision Knee System is an extended design of The Modal Manufacturing Total Knee System (K142649/K150783). It is a cobalt-chromium-molybdenum (Co-Cr-Mo) metallic baseplate with a variety of components including tibial augments, stems, and offset adapters that provide more choice for surgeon treatment of their patients. The CPM Medical Consultants posterior stabilized plus inserts is a line extension to the previously cleared Modal Manufacturing posterior stabilized tibial insert (K142649). The CPM Medical Consultants Tibial Revision Knee System is to be used in conjunction with the previously cleared Modal Manufacturing Total Knee System (K142649/K150783) which 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 Total Knee System 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 complimentarily 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.

Intended Use

The CPM Medical Consultants Tibial Revision Knee System 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 device is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require constrained stabilization for tibiofemoral joint due to soft tissue in-balance. The tibial augments are to be attached to their respective components with a fixation screw or screws.

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CPM Medical Consultants Tibial Revision Knee System

Compatibility Chart

		CPM Medical Consultants Tibial Revision Components			
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Progressive Orthopaedic Company Components	CR Femoral				
	PS Femoral				
	CR Tibial Insert				
	PS Tibial Insert				
	Tibial Tray				
	Patella				

Compatible Non-Compatible

Summary of Technological Characteristics

The CPM Medical Consultants Tibial Revision Knee System is similiar to the predicate Modal Manufacturing 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).

Performance Testing

Extensive preclinical performance testing was conducted on the CPM Medical Consultants Tibial Revision Knee System and substantial equivalence to the predicate device was determined. The components of the subject device are similar to the predicate device, and therefore the predicate device testing demonstrates substantial equivalence for the subject device. The results confirm that all components of the CPM Medical Consultants Tibial Revision Knee System exhibit the appropriate mechanical characteristics for tibial revision 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 utilizing Modal Manufacturing design and testing.
- Shear fatigue strength of the tibial insert post utilizing Modal Manufacturing design and testing.

- Tibiofemoral contact area and stress utilizing Modal Manufacturing design and testing.
- Tibiofemoral constraint utilizing Modal Manufacturing design and testing.
- Taper Lock Testing

Conclusions

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 CPM Medical Consultants Tibial Revision Knee System is safe for clinical use.

The CPM Medical Consultants Tibial Revision Knee System is substantially equivalent to the predicate device.