September 2, 2025

Ignite OrthoMotion
Russell Parrott
Chief Technology Officer
700 Park Avenue
Suite F
Winona Lake, Indiana 46590

Re: K251975
Trade/Device Name: Achieve Partial Knee System - Porous Coated CoCrMo Femoral Component
Regulation Number: 21 CFR 888.3535
Regulation Name: Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Codes: NJD, HSX
Dated: June 26, 2025
Received: June 26, 2025

Dear Russell Parrott:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2025.09.02 16:36:09 -04'00'

For Lixin Liu, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251975

Device Name

ACHIEVE PARTIAL KNEE SYSTEM - POROUS COATED CoCrMo FEMORAL COMPONENT

Indications for Use *(Describe)*

The ACHIEVE PARTIAL KNEE SYSTEM is intended for unicompartmental knee arthroplasty of the medial and/or lateral femorotibial compartments to treat one or more of the following conditions:

- Moderately disabling joint disease of the knee resulting from painful osteo or post traumatic arthritis.
- Revision of previous unsuccessful surgical procedures, including prior unicompartmental knee arthroplasty.
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

Fixation Methods
Tibial trays and femoral components with engineered porous surfaces are intended for cemented or cementless use.

Tibial trays and femoral components without engineered porous surfaces are intended 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"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."

510(k) Summary

Prepared: June 26, 2025

Submitter:
Ignite OrthoMotion, LLC
700 Park Ave.
Suite F
Winona Lake, IN 46590

Contact:
Russ Parrott
Chief Technology Officer
Phone: 574.527.2864
russ.parrott@igniteorthopedics.com

Proprietary Name: ACHIEVE™ Partial Knee System – Porous Coated CoCrMo Femoral Component

Common Name: Unicompartmental Knee Replacement System

Classification: Knee joint femorotibial (uni-compartmental) metal/polymer porous coated uncemented prosthesis; (21 CFR §888.3535); Class II

Knee joint femorotibial metal/polymer non-constrained cemented prosthesis; (21 CFR §888.3520); Class II

Product Codes: NJD, HSX

Predicate Devices: K242307(Primary) - ACHIEVE Partial Knee System, Ignite OrthoMotion

Reference Devices:
K243768 – iTotal Identity Cruciate Retaining 3DP Porous Knee Replacement System, Encore Medical, restor3d, inc.
K210308 – EMPOWR Porous Femur with HA^{nano} Surface, Encore Medical
K190085 – Journey II Unicompartmental Knee System, Smith & Nephew, Inc.
K202716 – Ignite Anatomic Shoulder System, Ignite Orthopedics LLC

Device Description:

The subject ACHIEVE™ Partial Knee System – Porous Coated CoCrMo Femoral Component is a line extension to the ACHIEVE™ Partial Knee System (cleared via K242307). The line extension is primarily focused on the addition of a Porous Coated Cobalt Chromium Molybdenum (CoCrMo) Femoral Component into the system, but also includes some minor modifications to material, manufacturing location, and design of the Femoral Components and Tibial Trays, which were previously cleared in K242307. The Instructions for Use and Surgical Technique were updated to account for the material changes of the subject devices. The indications for use were also updated to clarify that the device is intended for use in the medial and/or lateral compartment of the tibiofemoral joint.

The ACHIEVE™ PARTIAL KNEE SYSTEM – POROUS COATED COCRMO FEMORAL COMPONENT is a knee joint femorotibial (unicompartmental) prosthesis that is intended for cementless or cemented fixation. The implant system consists of individually packaged implants: a metal tibial tray (titanium alloy), a polyethylene tibial insert, and a metal femoral component (titanium alloy or cobalt-chromium). The tibial trays and femoral components with HA^{nano} Surface™ have an adjunct coating of hydroxyapatite (HA) on the engineered porous surfaces. All tibial inserts are composed of a Cross-linked, Vitamin E Ultra High Molecular Weight Polyethylene (Cross-Linked, VE UHMWPE).

Indications for Use:

The ACHIEVE PARTIAL KNEE SYSTEM is intended for unicompartmental knee arthroplasty of the medial and/or lateral femorotibial compartments to treat one or more of the following conditions:

- Moderately disabling joint disease of the knee resulting from painful osteo or post traumatic arthritis.
- Revision of previous unsuccessful surgical procedures, including prior unicompartmental knee arthroplasty.
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

Fixation Methods

Tibial trays and femoral components with engineered porous surfaces are intended for cemented or cementless use.

Tibial trays and femoral components without engineered porous surfaces are intended for cemented use only.

Summary of Technologies/Substantial Equivalence:

The implants and associated instruments within the ACHIEVE™ Partial Knee System are substantially equivalent to the primary predicate device in terms of its intended use and indications, material, design, sizes, and mechanical properties. Differences between the subject device system and the predicate device system do not raise different questions of safety and effectiveness.

Non-Clinical Testing:

The ACHIEVE™ Partial Knee System underwent non-clinical testing and analyses to support a determination of substantial equivalence to the predicate device. A review of the worst-case assessment in the protocol and/or the test results, indicate that the subject ACHIEVE Partial Knee implants are equivalent to the existing, legally marketed predicate devices with regards to mechanical performance and that there are no new issues related to the safety and effectiveness of the subject device. The following were completed:

Predicate Comparison Evaluation

A detailed comparison of key technologies and feature dimensions was made between the subject device and predicate devices. The comparison concluded the subject device key technologies and feature dimensions are substantially equivalent to that of the predicate devices.

Range of Motion (RoM) Evaluation

An evaluation was conducted to ensure the RoM of the worst-case subject device components meet established specifications per ASTM F2083. The RoM targets were met.

Femoral Fatigue Testing

Femoral fatigue testing was performed to 10 Mc per modified ASTM F3210. The acceptance criteria were met.

Tibial Tray Fatigue Testing

Tibial Tray fatigue testing was performed to 10 Mc per modified ASTM F3140. The acceptance criteria were met.

Component Interlock Strength Testing

To characterize the strength of attachment between the Tibial Tray and Tibial Bearing, static AP and ML shear testing and static tensile pull-off testing were performed. The acceptance criteria were met.

Evaluation of Wear Resistance

Wear testing was performed per ISO 14243-3. The wear rate of the subject device does not represent a new worst-case when compared directly to a predicate device.

Tibial-Femoral Contact Area/Contact Stress Testing

The contact surface areas and contact stresses were determined experimentally and an engineering justification demonstrated that the subject device does not represent a new worst-case for tibial-femoral contact area/contact stress when compared to the predicate devices.

Characterization of Titanium Articular Surface Coatings

The wear properties of the Titanium Nitride (TiN) coating of the articular surface were characterized and found to be substantially equivalent to an uncoated cobalt-chrome alloy (CoCrMo) when articulating with a UHMWPE bearing couple. An engineering justification demonstrated that the subject device does not represent a new worst-case for wear resistance, abrasion-resistance and surface hardness of the articulating surfaces when compared to the predicate device, which is made from CoCrMo.

Biocompatibility Assessments

The contact classification for the subject devices is Implant, Bone/Tissue with permanent contact (>30 days). A Biocompatibility Assessment was completed and provided per ISO 10993-1 and FDA Guidance Document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. The devices were found to be biocompatible.

Porous Structure Characterization

The porous structure used for the subject device was evaluated per ASTM F1044 (Static Shear Strength), ASTM F1147 (Static Tensile Strength), ASTM F1160 (Shear Fatigue), ASTM F1978 (Abrasion Resistance), and ASTM F1854 (Stereological Evaluation). The engineered porous structure meets the recommendations of the Class II Special Controls Guidance Document: Knee Joint Patellfemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA.

Shelf-Life Evaluation

A shelf-life evaluation per ISO 11607-1 and ISO 11607-2 was completed on the packaging materials that make up the sterile barrier. A five-year shelf life was established based on the resultant data.

Sterilization Validation

Sterilization validation was completed using the VDmax method specified in ISO 11137-1 and ISO 11137-2. The Sterility Assurance Level (SAL) was found to be 10^{-6}.

Clinical Testing:
Clinical testing was not necessary to demonstrate substantial equivalence of the ACHIEVE™ Partial Knee System – Porous Coated CoCrMo Femoral Component to the predicate device.

Conclusion:

A comparison of the subject and predicate devices, including comparison of the intended use, indications for use, technological characteristics, and non-clinical testing results has demonstrated that the subject device has a safety and effectiveness profile equivalent to that of the predicate device.
Thus, the subject device is substantially equivalent to the predicate device.