November 3, 2023

Amplitude
℅ J.D. Webb
President
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven, Utah 84401

Re: K230078
Trade/Device Name: TRAX® CR Total 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: October 30, 2023
Received: October 30, 2023

Dear J.D. Webb:

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.

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,

Lixin Liu -S

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230078

Device Name

TRAX® CR Total Knee System

Indications for Use *(Describe)*

The TRAX® CR Total Knee System is indicated for use:
- In primary total knee arthroplasty (TKA) as a result of:
  • Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
  • Post-traumatic loss of knee joint configuration and function.
  • Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- In revision of previous osteotomy,
- In revision of previous unsuccessful unicompartimental or femoro-patellar knee.

The TRAX® CR Total Knee System is for single use only and is intended for implantation with bone cement 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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510(k) Summary

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Amplitude is hereby submitting this 510(k) Summary.

Date Prepared

October 31, 2023

Submitter [510(k) owner]

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Primary Contact

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Submitted Device Information

Trade Name: TRAX® CR Total Knee System
Common Name: Total knee

Classification Information

Classification: Class II
Regulation Number: 21 CFR 880.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis

Product Code: JWH
Device Panel: Orthopedic

Legally Marketed Predicate Devices

The TRAX® CR Total Knee System manufactured by Amplitude is substantially equivalent to the following device currently in commercial

Primary Predicate Device

Device:	Persona Knee System
Company:	Zimmer-Biomet
510(k) number:	K113369/K193223

Secondary Predicate Device

Device:	Anatomic Total Knee System
Company:	Amplitude
510(k) number:	K161414

Submitted Device Description

The TRAX® CR Total Knee System belongs to the category of Cruciate Retaining (CR) total knee prostheses (only anterior-cruciate is sacrificed).

The TRAX® CR Total Knee System is intended for use as a semi-constrained replacement system. It consists of a femoral component, a tibial implant and a patellar component. The tibial implant consists of two components: bearing insert and tibial baseplate. The patellofemoral joint may be preserved or resurfaced with the patellar resurfacing implant.

The selection of the appropriate implants can be made by using the recommendations of the surgical

technique and by using the x-ray templates and trial implants supplied with the instrumentation.

Materials

CoCrMo alloy (ISO 5832-4)

Antioxidant (vitamin E) doped highly crossed linked polyethylene (AO-XLPE or A.X.P.E) (ASTM F648-14, ASTM F2565-13 and ASTM F2695-12)

Stainless-steel alloy according to ISO 5832-9 (M30NW)

Indications for Use

The TRAX® CR Total Knee System is indicated for use:

In primary total knee arthroplasty (TKA) as a result of:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.

In revision of previous osteotomy,

In revision of previous unsuccessful unicompartimental or femoro-patellar knee.

The TRAX® CR Total Knee System is for single use only and is intended for implantation with bone cement only.

Substantial Equivalence

The TRAX® CR Total Knee System is substantially equivalent to the predicate device in terms of intended use, design, manufacturing materials, principles of operation, and technical characteristics and raises no different issues of safety or effectiveness.

Summary of the Technological Characteristics Compared to Predicate

Intended Use

The TRAX CR and Persona are cruciate retaining knees to be used in total knee arthroplasty, revision of previous osteotomy, or revision of previous unsuccessful unicompartmental or femoro-patellar knee.

Materials

All femoral components are fabricated from CoCrMo per ISO 5832-4. The TRAX CR and ANATOMIC tibial baseplates are manufactured using CoCrMo per ISO 5832-4. Tibial inserts and patella components of the TRAX CR are manufactured from Vitamin E doped highly crossed linked polyethylene. Standard keels and extension keels are manufactured from CoCrMo per ISO 5832-4.

Design

The TRAX CR and Persona are cruciate retaining knees with anatomic (right/left) femoral components and tibial baseplates. All femoral components have a single radius of curvature. All baseplates have delta shaped keels. All devices have patellas that are spherical dome shaped.

Dimensions

The TRAX CR implants have similar dimensions as the predicates.

Anchorage to bone:

All systems are for implantation with bone cement.

Non-clinical Test Summary

Bench testing outlined below was conducted according to FDA guidance documents:

- Disassembly forces for tibial baseplate and insert per ASTM F1814-15
- Tibio-femoral constraint per ASTM F1223-20
- Tibio-femoral contact stresses per ASTM F2083-2
- Tibio-femoral wear per ISO 14243-1 (2009)

- Baseplate fatigue per ASTM F1800-19
- Patello-Femoral Constraint per ASTM F1223-20
- Patello-Femoral contact area stress per ASTM F2083-21
- Stem interlock strength per ASTM F1800-19
- Characterization of AXPE polyethylene per ASTM F2759-19
- MRI compatibility testing per ASTM F2052-2021
- Biocompatiblity testing per ISO 10993

Clinical Test Summary

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Conclusions:

Amplitude considers the TRAX CR Total Knee System to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.