September 6, 2024

implantcast GmbH
% Dave McGurl
Vice President, Regulatory Affairs - Orthopedics
MCRA, LLC
803 7th St NW, Floor 3
Washington, District of Columbia 20001

Re: K234044
Trade/Device Name: ACS® LD FB 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: August 6, 2024
Received: August 6, 2024

Dear Dave McGurl:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234044

Device Name

ACS® LD FB Knee System

Indications for Use *(Describe)*

General total knee arthroplasty indications include:

• 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
• Revision of previous unsuccessful knee replacement or other procedure, where soft tissue stability is adequate
• Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques

The posterior stabilized variant is also indicated for PCL instability requiring implant bearing surface geometries with increased anterior-posterior constraint and absent or non-functioning posterior cruciate ligament.

The ACS® LD FB Knee System is intended for cemented use, single use only.

The ACS® LD FB Knee System is intended for use in total knee arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged knee joint articulation where there is evidence of sufficient sound bone to seat and support the components.

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.

510(k) Summary

Device Trade Name: ACS® LD FB Knee System

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Date Prepared: December 20, 2023

Classification: 21 CFR §888.3560 - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Class: II

Product Code: JWH

Primary Predicate Device: *Corin USA Limited* Unity™ Total Knee System (K173884)

Additional Predicate Devices: *Stryker Corporation* Scorpio® NRG and Scorpio® TS Knee Systems (K994128, K011643, K041591, K042343)
Medacta International, SA GMK® Primary and GMK® Revision Knee Systems (K090988, K102437)

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General total knee arthroplasty indications include:

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Device Description:
The ACS® LD FB Knee System is a modular knee replacement system offering various components that can be combined to replace the knee joint with various options depending upon the size and anatomy of each patient. The ACS® LD FB Knee System consists of:

- ACS® LD Femoral Components
  - ACS® LD Femoral Component
  - ACS® LD Femoral Component Slim
  - ACS® LD PS Femoral Component Slim
  - ACS® LD PS Femoral Component
  - ACS® LD SC Femoral Component
- ACS® LD FB+ Tibial Components
  - ACS® LD FB+ Tibia
  - Locking Plug for ACS® FB Tibial Component
  - Cone Plug for ACS® FB Tibial Component
- ACS® FB+ PE-Inserts
  - ACS® FB+ PE-Insert
  - ACS® FB+ PE-Insert Hyperflex
  - ACS® FB+ PE-Insert Ultra
  - ACS® FB+ PS PE-Insert Hyperflex
  - ACS® FB+ SC PE-Insert
- ACS® Double Taper
- ACS® Stem
  - ACS® LD Extension Stem Male Taper
  - ACS® Stem
- ACS® Spacers
  - ACS® FB Tibial Spacer
  - ACS® FB screw for spacer
  - MK Femoral Spacer

    - MK Screw for Spacer
- ACS® Patella Replacements
    - ACS® PE-Patella

The ACS® LD FB Knee System is available as a non-coated (LD) fixed bearing (FB) version. The tibial and femoral components are available in cemented version.

Substantial Equivalence:
The ACS® LD FB Knee System is substantially equivalent to the predicate devices cited on the previous page with respect to intended use, design, and materials.

Performance Testing:
All necessary testing has been performed for the worst-case configuration of the ACS® LD FB Knee System to assure substantial equivalence to its predicates and to demonstrate the subject devices perform as intended. All testing was performed on test units representative of finished devices. The performance of the ACS® LD FB Knee System was characterized through the following tests:

- Femoral Fatigue Testing (ASTM F2083)
- Tibial Fatigue Testing (ASTM F1800)
- Fatigue Testing of Tapers and Augments (ASTM F1875)
- Interlocking Strength (ASTM F1814)
- Patellofemoral Constraint Testing (ASTM F1223)
- Patellofemoral Contact Area and Pressure Testing (ASTM F2083)
- Posterior Stabilized Shear Fatigue Testing (ASTM F2083)
- Cone Connection Testing (ASTM F2722)
- Tibiofemoral Constraint Testing (ASTM F1223)
- Tibiofemoral Contact Area and Pressure Testing (ASTM F2083)
- Range of Motion Evaluation (ISO 21536)

Conclusion:
The ACS® LD FB Knee System possesses the same intended use and similar technological characteristics as the predicate devices. Therefore, the ACS® LD FB Knee System is substantially equivalent to the cited predicate devices.