January 8, 2021

Implantcast GmbH
% Dave McGurl
Director, Spine Regulatory Affairs
MCRA, LLC
1050 K Street NW Suite 1000
Washington, District of Columbia 20001

Re: K203341
Trade/Device Name: ACS® LD Uni FB Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: November 12, 2020
Received: November 12, 2020

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 (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)*
K203341

Device Name
ACS® LD Uni FB Knee System

Indications for Use *(Describe)*
The ACS® LD Uni FB Knee System is indicated for partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

This device is single-use implant intended for implantation with bone cement.

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.

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5. 510(K) SUMMARY

Device Trade Name: ACS® LD Uni FB Knee System

Manufacturer:
implantcast, GmbH
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2164 Buxtehude, Germany

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Date Prepared: August 24, 2020

Classification: 21 CFR §888.3520, Knee joint femorotibial metal/polymer non-constrained cemented prosthesis

Class: II

Product Code: HSX

Predicate Devices:
Biomet Repicci II® Unicondylar Knee (K063515)
Bodycad Unicompartmental Knee System (K163700, K181302)
Medacta GMK® UNI (K161741)
Zimmer Unicompartmental Knee System (K033363)

Indications for Use:
The ACS® LD Uni FB Knee System is indicated for partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

This device is single-use implant intended for implantation with bone cement.

Device Description:
The ACS® LD Uni FB Knee System is a unicondylar knee replacement system. It is intended for patients with unicompartmental osteoarthritis and intact cruciate and collateral ligaments.

The ACS® LD Uni FB Knee System consists of the following components:

- ACS® Uni LD Femoral Component
- Uni FB Tibial Component
- Uni FB PE-Insert

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

Performance Testing:
All recommended testing has been performed for the worst-case configuration of the ACS® LD Uni 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 Uni FB Knee System was characterized through the following tests:

- Constraint Testing (ASTM F1223)
    - Medial-lateral and anterior-posterior displacement, rotary-laxity rotation
- Contact Area / Stress (ASTM F2083)
- Fatigue Testing Tibia (ASTM F3140-17)
- Interlocking Strength (ASTM F2083, ASTM F1814)
    - Anterior-posterior, posterior-anterior, medial-lateral and lateral-medial
- Range of motion evaluation

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