September 27, 2018

RootLoc Co., Ltd.
Jungsun Ha
RA Specialist
#1206, 1210, 68, Digital-ro 9-gil
Geumcheon-gu, Seoul, 08512, Korea

Re: K182370
Trade/Device Name: Acculoc 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: August 28, 2018
Received: August 31, 2018

Dear Jungsun Ha:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
2018.09.27 11:34:52 -04'00'

FOR Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K182370

Device Name
Acculoc Total Knee System

Indications for Use *(Describe)*

The Acculoc Total 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, avascular necrosis of the femoral condyle, posttraumatic loss of joint configuration. Moderate valgus, varus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability. This device may also be indicated in correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure. The Acculoc Total Knee System is designed 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.

Special 510(k) SUMMARY

The following Special 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1.

Submitter: RootLoc Co., Ltd.
#1206, 1210, 68, Digital-ro 9-gil
Geumcheon-gu, Seoul, 08512, Korea
Phone. 82-2-6941-4341
e-mail: jsha0314@gmail.com

Contact Person: Jungsun Ha

Date prepared: August 28, 2018

2. Device Identification

Trade Name	Acculoc Total Knee System.
Common Name	PROSTHESIS, KNEE, PATELLOFEMOROTIBIAL, SEMI-CONSTRAINED, CEMENTED, POLYMER/METAL/POLYMER
Product Code	JWH
Regulatory Class	2
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21CFR 888.3560. This falls under the Orthopedics panel/87 as a ClassⅡ device.

3. Purpose of 510(k)

The RootLoc Co., Ltd. here by submits this Special 510(k) for adding CoCrMo alloy(ASTM F75) Tibial tray with the same size and design as the predicate device cleared under Acculoc Total Knee System (K170753).The intended use of the added (Acculoc Tibial tray) has not changed as result of addition.

4. Indication for Use

Acculoc Total 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, avascular necrosis of the femoral condyle, posttraumatic loss of joint configuration. Moderate valgus, varus, or flexion deformity in which the ligamentous structures can be returned to adequate

function and stability. This device may also be indicated in correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure. The Acculoc Total Knee System is designed for cemented use only.

5. Predicate or legally marketed devices which are substantially equivalent

Predicate:

Primary predicate: Acculoc Total Knee System (K170753)

Reference predicate: Corentec EAUM/LOSPA TKR System (K110404, K130673)

6. Description of the Device

The Acculoc Tibial tray is a component of "Acculoc Total Knee System" cleared under K170753 which consist of Femoral component, Tibial tray, Tibial Insert, Patella components and Instrumentation- Acculoc Total Knee Instrumentation System for use with the implants components.

The current premarket notification is related to the addition of the Acculoc Tibial tray manufactured from CoCrMo alloy (Cobalt-chromium-molybdenum alloy), this is same size and same design with the predicate device tibial tray (K170753) and only the material is different.

The Tibial tray AP and ML size ranges are exact same as the predicate device Tibial tray (K170753).

Acculoc Total Knee system Materials:

Product	Material	Standard
Femoral component	CoCrMo Alloy	ASTM F75
Tibial Tray component	Ti-6Al-4V ELI	ASTM F136
	CoCrMo Alloy (Added)	ASTM F75
Tibial Insert component	UHMWPE (GUR 1050)	ASTM F648
Patella component	UHMWPE (GUR 1050)	ASTM F648

7. Comparison of the technological characteristics of the subject and predicate devices

Acculoc Tibial tray is substantially equivalent in indications and design principles to the predicate devices, each of which has been determined by FDA to be substantially equivalent as below

- Primary predicate: Acculoc Total Knee System (K170753)
- Reference predicate: Corentec EAUM/LOSPA TKR System (K110404, K130673)

8. Performance Testing

Performance testing was carried out to demonstrate substantial equivalence and included methods described in the following standards: ASTM F1800/ISO14879-1. Mechanical testing of the subject device consisted of fatigue testing and performed similar to the predicate device/s and pyrogenicity testing has been conducted.

9. Conclusion

The Acculoc Tibial tray has similarities to the predicate device/s with the same intended use, same fundamental scientific technology, same operating principles, same material and are same sterile.