



June 23, 2016

Excera Orthopedics, Incorporated
% Mr. Kellen Hills
Quality and Regulatory Consultant
Orchid Design
4600 East Shelby Drive
Memphis, Tennessee 38118

Re: K153057

Trade/Device Name: FitRite™ Total Hip Arthroplasty System
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI
Dated: May 17, 2016
Received: May 20, 2016

Dear Mr. Hills:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Vincent J. Devlin -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153057

Device Name

FitRite™ Total Hip Arthroplasty System

Indications for Use (Describe)

The FitRite™ Total Hip Arthroplasty System is indicated for total hip replacement in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The FitRite™ DDH Femoral Stems, Standard Femoral Stems, and Acetabular Cups are intended for cementless application; the FitRite™ Cemented Femoral Stems are intended for cemented application.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

[As Required by 21 CFR 807.92]

- (a)(1) Submitted By: Excera Orthopedics, Inc.,
1188 Centre St,
Newton, MA 02459
Phone: 901-433-1990
Fax: 901-433-1989
Date: May 17, 2016
Contact Persons
Primary: Kellen Hills (Orchid Design Consulting)
Secondary: Scott Coleridge (Excera Orthopedics, Inc)
- (a)(2) Proprietary Name: FitRite™ Total Hip Arthroplasty System
Common Name: Total Hip Prosthesis
Classification Name and Reference: 21CFR 888.3350-Hip joint metal/polymer semi-constrained cemented prosthesis
Product Code: JDI
- (a)(3) Predicate Devices:
Primary: FitRite™ Total Hip Arthroplasty System (K140547)
- (a)(4) Device Description:
The FitRite™ Total Hip Arthroplasty System (THA) system is used for primary total hip replacement in skeletally mature individuals. The system consists of uncemented and cemented femoral stems, CoCr femoral heads in various sizes and offsets, uncemented acetabular cups and conventional polyethylene liners. Instrumentation necessary for proper implantation is also included.

The purpose of this submission is to introduce additional sizing of the cemented stems.
- (a)(5) Indications for Use:
The FitRite™ Total Hip Arthroplasty System is indicated for total hip replacement in the following conditions:
1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The FitRite™ DDH Femoral Stems, Standard Femoral Stems, and Acetabular Cups are intended for cementless application; the FitRite™ Cemented Femoral Stems are intended for cemented application.
- (a)(6) Comparison of Technological Characteristics:

The FitRite™ Total Hip Arthroplasty System is substantially equivalent to the previously cleared predicate devices based on similarities in intended use, design, materials, manufacturing methods, packaging, sterilization and mechanical performance. The technological characteristics do not raise any new questions of safety and efficacy.

(b)(1) Non-clinical testing:

Engineering analysis was used to demonstrate that the new sizes of cemented stems do not introduce a new worst case and prior testing conducted on the predicate system demonstrate conformity to the applicable standards.

(b)(2) Clinical testing:

Clinical testing was not required to demonstrate substantial equivalence in this premarket notification.

(b)(3) Conclusions:

Based on the information provided in this premarket notification, we believe that the subject FitRite™ Total Hip Arthroplasty System demonstrates substantial equivalence to the identified predicate devices.