



February 26, 2016

ICONACY Orthopedic Implants, LLC  
Roy Y. Hori  
Executive Vice President, Product Development  
4130 Corridor Drive  
Warsaw, Indiana 46582

Re: K151307

Trade/Device Name: ICONACY™ I-Hip™

Regulation Number: 21 CFR 888.3353

Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Regulatory Class: Class II

Product Code: LZO

Dated: December 24, 2015

Received: December 30, 2015

Dear Mr. Hori:

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,

**Lori A. Wiggins -S**

for  
Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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## Indications for Use

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510(k) Number (if known): K151307

**Device Name:** ICONACY™ I-Hip™

### Indications for Use:

The ICONACY I-Hip is indicated for the following conditions: (1) a severely painful and/or disabled hip joint as a result of 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, (6) nonunions, correction of functional deformity, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The ICONACY I-Hip consists of femoral stem and acetabular cup (i.e. shell) porous coated components intended for cementless, press-fit fixation.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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**510(k) Summary**

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**PREPARED:** December 24, 2015

**510(k) SPONSOR:** ICONACY Orthopedic Implants, LLC  
4130 Corridor Drive  
Warsaw, IN 46582

**CONTACT PERSON:** Roy Y. Hori  
Executive Vice President, Product Development  
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(574) 269-4622 or (574) 306-2450

**TRADE NAME:** ICONACY™ I-Hip™

**COMMON NAMES:** Total Hip System

**REGULATION and CLASS:** Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prostheses (21 CFR Section 888.3353, Class II)

**PRODUCT CODE:** LZ0

**PREDICATE DEVICES:**

- Zimmer BioloX delta Ceramic Femoral Head, K071535
- ICONACY I-Hip Total Hip System, K121034
- ICONACY I-Hip Total Hip System (RS Acetabular Cups and Rings), K131279
- ICONACY I-Hip Total Hip System (Gradual Transitioning Femoral Stems), K133228
- ICONACY I-Hip Total Hip System (Additional Acetabular Liners, Apex Hole Plug), K132572

**DEVICE DESCRIPTION:**

The ICONACY I-Hip consists of a collarless, tapered, forged titanium alloy femoral stem mated to a modular femoral head. This femoral construct articulates with an acetabular device assembly. The acetabular device assembly consists of a hemispherical titanium alloy cup (i.e., shell) coupled with a highly cross-linked ultra-high molecular weight polyethylene (HXL-UHMWPE) liner. Forty percent of the femoral stem is circumferentially coated with

a titanium coating designed to attain a cementless, press-fit fixation. The acetabular cup is machined from forged Ti-6Al-4V ELI alloy. The cup has a threaded polar hole for insertion. The outer hemispheric surface of the cup has a titanium plasma spray coating for cementless, press-fit fixation. Titanium bone screws may be used for additional fixation. A titanium locking ring is fixed into grooves on the cup to engage grooves on the HXL-UHMWPE liner. Standard instrumentation is used to implant the device.

The current submission adds ceramic femoral heads in 28, 32 and 36mm diameters and modified CS Acetabular Liners to the system. Compatible femoral stems, acetabular cups, locking rings, bone screws and apex hole plug were cleared in K121034, K131279, K133228 and K132572.

**INDICATIONS FOR USE:** The ICONACY I-Hip is indicated for the following conditions: (1) a severely painful and/or disabled hip joint as a result of 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, (6) nonunions, correction of functional deformity, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The ICONACY I-Hip consists of femoral stem and acetabular cup (i.e. shell) porous coated components intended for cementless, press-fit fixation.

**BASIS FOR SUBSTANTIAL EQUIVALENCE:** The ICONACY I-Hip Ceramic Femoral Heads and CS Acetabular Liners are substantially equivalent to the predicate devices based on similarities in material, design, sizing, mechanical strength and indications for use.

**PERFORMANCE DATA:** Pre-fatigue burst, fatigue, post-fatigue burst, pull-off, wear testing, wear testing under adverse conditions and biocompatibility testing confirm that the ICONACY I-Hip Ceramic Femoral Heads and CS Acetabular Liners meet pre-determined acceptance criteria and are expected to be safe and effective for the proposed indications.

**CLINICAL TESTING:** Clinical testing was not required to determine substantial equivalence with the predicate devices.