



Food and Drug Administration  
10903 New Hampshire Avenue  
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Iconacy Orthopedic Implants, LLC  
% Ms. Carol Vierling  
President  
C L Vierling, LLC  
3560 Greystone Drive  
Warsaw, Indiana 46582

April 8, 2016

Re: K160266

Trade/Device Name: ICONACY™ I-Hip™

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Regulatory Class: Class II

Product Code: LPH

Dated: March 23, 2016

Received: March 24, 2016

Dear Ms. Vierling:

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,

**Mark N. Melkerson -S**

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)  
K160266

Device Name  
ICONACY™ I-Hip™

Indications for Use (Describe)

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.

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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**510(k) Summary**

## I. SUBMITTER

ICONACY Orthopedic Implants, LLC  
4130 Corridor Drive  
Warsaw, IN 46582

**Contact Person:** Thomas R. Allen

**Telephone Number:** (574) 453-6567

**Fax Number:** (866) 685-8226

**Date Prepared:** March 17, 2016

## II. DEVICE

**Proprietary Name:** ICONACY™ I-Hip™

**Common Name:** Total Hip System

**Regulation:** 21 CFR 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

**Class:** II

**Panel:** Orthopedics

**Product Code:** LPH

## III. PREDICATE DEVICES

ICONACY™ I-Hip™ Total Hip System, K121034

ICONACY™ I-Hip™ Total Hip System, K131279

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

## IV. DEVICE DESCRIPTION

The ICONACY I-Hip consists of a collarless, tapered, forged titanium alloy femoral stem mated to a cobalt chrome alloy modular femoral head. Forty percent of the femoral stem is circumferentially coated with a titanium coating

designed to attain a cementless, press-fit fixation. This femoral construct articulates with an acetabular device assembly.

The acetabular device assembly consists of a hemispherical titanium alloy cup coupled with a highly cross linked ultra-high molecular weight polyethylene (HXL-UHMWPE) liner. The acetabular cup is machined from forged Ti-6Al-4V ELI alloy and is available in standard, finned and spike configurations. The acetabular cup has a threaded polar hole for insertion. The standard and finned cups have screw holes for additional fixation.

The outer hemispheric surface of the acetabular cup has a titanium plasma spray coating for cementless, press-fit fixation. A titanium locking ring is fixed into a groove on the cup to engage a groove on the HXLUHMWPE liner. Standard instrumentation is used to implant the device.

The current submission addresses modifying the standard and finned acetabular cups to add a third screw hole. The acetabular cup materials, porous coating and indication for use remain the same. No additional sizes are being added to the product line. No new instruments are required. The spiked cups are unchanged with no screw holes.

The compatible femoral stems, femoral heads, acetabular liners and bone screws remain unchanged from those cleared under K121034.

## V. INDICATION 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.

No changes are being made to the indication for use.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The original ICONACY I-Hip was cleared under K121034. The acetabular cups described in that submission had two screw holes for additional fixation (standard acetabular cups). Under K131279, spiked and finned cups were added to the I-Hip System (in the same sizes as those described in K121034), again with two screw holes for additional fixation. The modification that is the subject of this 510(k) is the addition of a third screw hole to the standard and finned acetabular cups. The spiked acetabular cups remain with no screw holes.

The acetabular cup materials, porous coating and indication for use remain the same. No additional sizes are being added to the product line. No new instruments are required. The compatible femoral stems, femoral heads, acetabular liners and bone screws remain unchanged from those cleared under K121034.

## VII. PERFORMANCE DATA

Finite Element Analysis (FEA) confirmed that adding a third screw hole to the acetabular cups had little impact on cup stiffness.

Clinical testing was not required to establish equivalency of the device.

## VIII. CONCLUSIONS

The modified acetabular cups utilize the same fundamental scientific technology, are made of the same materials, mate with the same femoral components and bone screws and have the same indication for use as the predicate standard and finned acetabular cups of the ICONACY I-Hip. The non-clinical testing demonstrates that adding a third screw hole does not raise any new questions of safety or effectiveness. Therefore, the modified acetabular cups of the ICONACY I-HIP are substantially equivalent to the predicate devices.