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FEB - 7 2014

510(k) SUMMARY

K132539

Ring-Lok™ Modular Bipolar System

31 January 2014

1. Submitter: Implants International Limited
71 Jay Avenue
Teeside Industrial Estate
Thornaby-on-Tees, TS17 9LZ UK

Contact: Trudie Seeger, PhD
U.S. Agent
614-876-6374(p)
614-876-6621(f)

2. Device Name

Proprietary Name:	Ring-Lok™ Modular Bipolar System
Common Name:	Hemi-hip prosthesis, uncemented
Classification Name:	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class:	Class II per 21 CFR §888.3390 (Product Code KWY)

3. Indication for Use

The Ring-Lok Hip System Bipolar Head is intended for use in combination with other previously cleared femoral components including the Rig-Fix™ Hip Stem (K072101), C-fit Performa (K923898) or the Stability Hip Stem (K915787 and K934457)) for uncemented primary or revision hemi-arthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur
- Osteonecrosis of the femoral head
- Revision procedures where other treatments or devices or these indications have failed.

4. Device Description

The Ring-Lok™ Modular Bi-Polar System is intended for use in combination with the previously cleared femoral components including Rig-Fix™ Hip Stem (K072101), C-fit Performa (K923898) or the Stability Hip Stem (K915787 and K934457)). The Ring-Lok™ Modular Bipolar System consists of a factory assembled UHMWPE liner in a cobalt chrome outer shell, and UHMWPE retention ring. These bipolar heads include outer diameters ranging from 38 to 62 mm, in 1mm increments, to properly fit the patient anatomy. The inner diameter mates with a 22.225, 26 or 28 mm diameter femoral head.

Implant International supplies Ring-Lok™ Bi-Polar Instrumentation for use with the Ring-Lok™ Modular Bi-Polar System.

5. Predicate Device Comparison

Substantial equivalence is claimed to the Mèdacta Bi-Polar Head (K091967) and the BioPro Bi-Polar Head (K082705). The Ring-Lok™ Modular Bipolar System:

- Is the same technology (design and material) as the predicate devices
- Has the same or similar Indication for Use as the predicate devices
- Has the same functionality as the predicate devices
- Includes the same bipolar head inner and other dimensional sizes as the predicate devices
- Allows the head to snap-fit into the bipolar liner which is the same as one of the predicate devices (BioPro Bi-Polar Head)

6. Nonclinical Performance Testing

The Ring-Lok™ Modular Bipolar System was tested as part of design verification to written protocols with pre-defined acceptance criteria. Testing included Range of Motion, Lever Out and Pull Out tests conducted on the worst case component size and option/design. The testing met all acceptance criteria and verifies that the performance of the Ring-Lok™ Modular Bipolar System is substantially equivalent to the predicate devices.

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7. Conclusion

The information provided in this premarket notification demonstrates that the Ring-Lok™ Modular Bipolar System is as safe, as effective and performs as well as or better than the predicate devices, Medacta® Bi-polar Head and Bi-Pro Bipolar Head. This information supports the conclusion that Ring-Lok™ Modular Bipolar System is substantially equivalent to its predicate devices, with respect to intended use, design and operational principles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 7, 2014

Implant International Limited
% Trudie L. Seeger, Ph.D.
United States Agent
T. Leland Seeger & Associates
4170 Bowmansroot Court
Hilliard, Ohio 43026

Re: K132539
Trade/Device Name: Ring-Lok™ Modular Bi-Polar System
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: January 2, 2014
Received: January 6, 2014

Dear Dr. Seeger:

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 Part 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 Small Manufacturers, International and Consumer Assistance 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" (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 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 Small Manufacturers, International and Consumer Assistance 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

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): K132539

Device Name: Ring-Lok™ Modular Bi-Polar System

Indications for Use:

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- Revision procedures where other treatments or devices or these indications have failed.

Prescription Use X (21 CFR 801 Subpart D) and/or Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Frank -S

Division of Orthopedic Devices