



Food and Drug Administration
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Medacta International
% Mr. Michael G. Loiterman, MPD, RAC, CCEP
Director - Quality, Regulatory and Compliance
Medacta USA
1556 West Carroll Ave.
Chicago, Illinois 60607

October 30, 2015

Re: K151531

Trade/Device Name: MasterLoc Stem
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, LPH, MEH, KWY, LZY
Dated: October 5, 2015
Received: October 7, 2015

Dear Mr. Loiterman:

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 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)

K151531

Device Name

MasterLoc Stem

Indications for Use (Describe)

The hip prosthesis MasterLoc® is designed for cementless use in total or partial hip arthroplasty in primary or revision surgery.

Hip replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia;
- Avascular necrosis of the femoral head;
- Acute traumatic fracture of the femoral head or neck;
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

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)



510(k) Summary

Applicant/Sponsor: Medacta International SA
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Date Prepared: June 5, 2015

Device Information

Trade/Proprietary Name: MasterLoc Stem
 Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
 Regulation Number: 21 CFR 888.3353
 Device Class: Class II
 Classification Product Code: LZO
 Subsequent Product Codes: LPH, MEH, KQY, LZY

Primary Predicate Device:

510(k)	Product	510(k) Holder	Clearance Date
K052792	ANTHOLOGY Hip Stem	Smith & Nephew, Inc.	10/7/05

Additional Predicate Device:

510(k)	Product	510(k) Holder	Clearance Date
K072857	Medacta Total Hip Prosthesis	Medacta International	2/4/08

Product Description

A hip prosthesis consists of a femoral stem made of metal, a modular femoral head made of metal or ceramic, and acetabular components. The acetabular components consists of a metal cup, and a liner that is made of ultra-high molecular weight polyethylene (UHMWPE), or Highcross highly crosslinked ultra-high molecular weight polyethylene (HXUHMWPE). Acetabular components can be: Versafitcup, Versafitcup CC Trio, Mpact, Medacta Bipolar Head.

All the auxiliary components of the prosthesis are supplied in single-use individual packages.

The MasterLoc® stems can be combined with the CoCr ball heads, Endo Head or with the MectaCer BIOLOX® forte or MectaCer BIOLOX® delta femoral heads. Refer to the MectaCer BIOLOX® forte or MectaCer BIOLOX® delta femoral heads package insert and to CoCr heads package insert for more information about ball heads.

Indications for Use

The hip prosthesis MasterLoc® is designed for cementless use in total or partial hip arthroplasty in primary or revision surgery.

Hip replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia;
- Avascular necrosis of the femoral head;
- Acute traumatic fracture of the femoral head or neck;
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

Comparison to Predicate Devices

The indications for use, design features, materials of the MasterLoc Stem are substantially equivalent to those of the predicate devices. The substantial equivalence of the MasterLoc Stem implants is supported by the performance testing, materials information, and data analysis provided within this Premarket Notification.

Performance Testing

The MasterLoc Stem was tested as part of design verification to written protocols with pre-defined acceptance criteria. The MasterLoc Stem was tested using the worst-case component size and option/design for each of the following:

RISK	STANDARD
Risk of breakage of highly stressed parts of the stem	ISO 7206-4 (2010) ISO 7206-6 (2013)
Limited ROM	EN ISO 21535 (2009)
Risk of implant loosening due to a low strength of the adhesion and durability of the coating.	Internal
Instability of the modular connection	ASTM F2009-00 (2009)
Instability of the modular connection	ASTM F2009-00 (2009)
Risk of inadequate selection of predicate device.	Internal
Risk of instability. Risk of bone breakage due to lateral opening.	Internal

A review of the mechanical data indicates that the performance of the MasterLoc Stem is substantially equivalent to the predicate devices and is capable of withstanding expected in vivo loading without failure.

Conclusion:

Based on the above information, the MasterLoc Stem can be considered as substantially equivalent to its predicate devices.