DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 1, 2016

KYOCERA Medical Corporation
Ms. Cheryl Hastings
Official Correspondent
Uemura Nissei Bldg., 3-3-31 Miyahara
Yodogawa-ku
Osaka, 532-0003 Japan

Re: K160895
Trade/Device Name: Initia Total Hip System & BIOCERAM AZUL® HEAD
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
Dated: September 28, 2016
Received: September 29, 2016

Dear Ms. Cheryl Hastings:

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" (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 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 Statement

510(k) Number (if known): K160895

Device Name: Initia Total Hip System

Indications for Use:

The Initia Total Hip System is a single use total hip system for use in cementless hip arthroplasty procedures for the following indications:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results,

The Initia Total Hip System femoral stems are intended for cementless press-fit use. The Initia Total Hip System acetabular shells are intended for cementless use with biological fixation.

Prescription Use X (Part 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)

510(k) Number (if known): K160895

Device Name: BIOCERAM AZUL HEAD

Indications for Use:

The BIOCERAM AZUL HEAD is a single use modular femoral head component for use in hip arthroplasty procedures for the following indications:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Prescription Use __X____ (Part 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)

510(k) Summary

PREPARED: October 26, 2016

510(k) SPONSOR:
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TRADE NAMES:
Initia Total Hip System
BIOCERAM AZUL HEAD

COMMON NAMES:
Total Hip System
Modular Ceramic Femoral Head

CLASSIFICATION and CLASS:
21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, Class II

21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Class II

PRODUCT CODES: LZO, LPH

PREDICATE DEVICES:

- Biomet, Taperloc® 12/14 Taper Femoral Components (K043537)
- Howmedica Osteonics Accolade II Hip Stem (K120578)
- DePuy, Focus Total Hip System, Articul/eze Femoral Heads and Modular M Heads (K883460, K980513, K060031)
- Biomet, Porous Plasma Spray (PPS) Ringloc® + Acetabular System (K093235)
- DePuy Orthopaedics Pinnacle Acetabular System (K000306)
- Biomet ArcomXL Polyethylene Liners (K042051)
- DePuy, DePuy Pinnacle® AltrX™ Acetabular Liners (K072963, K102423)
- Medacta International Mectacer Biolox Delta Heads (K112115)
- Smith & Nephew, Reflection® Cross-linked UHMWPE Acetabular Components (K932755, K991026, K002747, K013658)
- Encore Orthopedics, 6.5 mm Cancellous Bone Screw (K931665)
- Howmedica Osteonics, Trident® Hip System (K033716)
- Howmedica Osteonics, Crossfire™ System 12® Acetabular Inserts (K993352)
- Howmedica Corp., Howmedica ® Acetabular Comp Pack/Manuf Meth (K934060)

DEVICE DESCRIPTION:

The Initia Total Hip System is comprised of femoral stems, Co-Cr femoral heads, acetabular shells, an apical hole plug, bone screws and crosslinked polyethylene acetabular liners.

The BIOCERAM AZUL® ceramic heads are zirconia toughened alumina (ZTA) ceramic femoral heads compatible with the femoral stems, acetabular shells and acetabular liners of the Initia Total Hip System.

The femoral stem is a monoblock wedge tapered design. It is manufactured from forged titanium alloy complying with ASTM F136 and ASTM F620 and is coated with a plasma spray of commercially pure titanium complying with ASTM F1580. The stem is offered in 19 stem sizes which include both standard and high offset neck options, for a total of 38 offerings.

The Co-Cr femoral head is manufactured from wrought Co-Cr complying with ASTM F1537. The head has a 12/14 taper bore and is available in outer diameters of 22, 26, 28, 32, 36, 40 and 44 mm. Each head diameter is available in multiple offset options.

The acetabular shell is also made from titanium alloy complying with ASTM F136. The acetabular shell is available in outer diameters ranging from 40 mm to 74 mm in 2 mm increments. The outer surface of the shell is coated with a plasma spray of commercially pure titanium complying with ASTM F1580. The acetabular shell is offered in 0 hole, 3 hole, and multi-hole configurations. Self-tapping acetabular bone screws can be used for initial shell

fixation. The screws are made from titanium alloy complying with ASTM F136. Bone screws are available in a 6.5 mm diameter and lengths from 15 to 60 mm in 5 mm increments. An apical hole plug, manufactured from titanium alloy complying with ASTM F136, is available to close the apical hole on the acetabular shell.

The acetabular liner is made from crosslinked ultra high molecular weight polyethylene (UHMWPE) complying with ASTM F648 and ASTM F2565. The polyethylene liner is offered in inner diameters of 22, 26, 28, 32, 36, 40 and 44 mm with outer diameters to fit the 40 – 74 mm acetabular shells. The liner is offered in 4 configurations: standard (STD), standard with offset (STD HO), elevated rim (MX), and elevated rim with offset (MX HO). The liner mates with the shell using a circumferential locking feature that is integrated into the liner to prevent disassociation. The locking feature mates with a circular groove machined into the shell. The liner also possesses anti-rotation tabs that mate with scallops in the shell.

The BIOCERAM AZUL® ceramic head is manufactured from high purity alumina matrix with zirconia reinforcement, which complies with ISO 6474-2. The head has a 12/14 taper bore and is available in outer diameters of 28, 32, 36, 40 and 44 mm. There are 3 offsets (-3.5, +0, +3.5 mm) for the 28 mm size. There are 4 offsets (-3.5, +0, +3.5, +7 mm) for the 32 to 44 mm sizes.

INDICATIONS FOR USE:

The Initia Total Hip System is a single use total hip system for use in cementless hip arthroplasty procedures for the following indications:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results,

The Initia Total Hip System femoral stems are intended for cementless press-fit use. The Initia Total Hip System acetabular shells are intended for cementless use with biological fixation.

The BIOCERAM AZUL HEAD is a single use modular femoral head component for use in hip arthroplasty procedures for the following indications:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

The Initia Total Hip System and the BIOCERAM AZUL® ceramic heads are substantially equivalent to the predicate devices based on similarities in intended use, indications for use, materials, design, sizing and mechanical strength.

PERFORMANCE DATA:

Mechanical testing confirmed that the Initia Total Hip System met pre-determined acceptance criteria for femoral stem neck fatigue, femoral stem distal stem fatigue, Co-Cr femoral head / femoral stem taper axial pull-off, fretting corrosion, acetabular shell / acetabular liner push-out, lever-out and torque-out, hip simulator wear, Mode 3 (with a roughened femoral head) hip simulator wear, wear particle analyses, impingement, bone screw torsional strength, insertion and removal torque and pull-out, and total hip range of motion.

Characterization testing included femoral stem and acetabular shell coating characterization and performance testing (static shear, static tensile, shear fatigue, abrasion resistance), and characterization of the crosslinked UHMWPE liner material in aged and unaged conditions as compared to predicate devices.

Biocompatibility testing was also conducted. Bacterial Endotoxin Testing was performed and the endotoxin limit of 20EU/device was met.

The BIOCERAM AZUL® ceramic heads met pre-determined acceptance criteria for static burst strength, fatigue, post-fatigue burst strength, axial pull-off, fretting corrosion, hip simulator wear, Mode 3 (with a roughened ceramic head) hip simulator wear and wear particle analyses.

CLINICAL TESTING:

Clinical testing was not required for determining substantial equivalence with the predicate devices.