K140043 APR 0 3 2014

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the DYNASTY® Acetabular System with Ceramic.

Submitted By:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 (866) 872-0211
Date:	April 4, 2014
Contact Person:	Matt Paul *Project Manager, Regulatory Affairs*
Proprietary Name:	DYNASTY® Acetabular System with Ceramic
Common Name:	Acetabular Shell, Acetabular Liner, Femoral Head
Classification Name and Reference:	888.3353 prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented Class II
Subject Product Code and Panel Code:	Orthopedics/87/LZO
Predicate Devices:	DYNASTY® Acetabular System with Ceramic 510(k): K130376 Shell: K002149; Liner: K052026; Head: K130376

DEVICE INFORMATION

A. Intended Use

MicroPort total hip systems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty. Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty.

B. Device Description

The DYNASTY® Acetabular System with Ceramic contains femoral heads in size 28mm manufactured from alumina matrix composite, mating acetabular liners manufactured from crosslinked polyethylene, and beaded acetabular shells manufactured from titanium alloy.

C. Substantial Equivalence Information

The subject DYNASTY® Acetabular System with Ceramic is indicated to be paired with the following existing acetabular components summarized in Table 1. These shell types were cleared in K130376 for use with larger diameter BIOLOX® DELTA ceramic-polyethylene bearings.

Table 1. Compatible Shells, Including 510(k) Information. All shells were cleared for use with Biolox Delta heads and polyethylene liners in K130376.

510(k)	Device Name
K122382	DYNASTY® 10 Hole Revision Shells
K122382	DYNASTY® BIOFOAM® 3-Hole Shells
K122382	DYNASTY® BIOFOAM® Solid Shells
K122382	DYNASTY® BIOFOAM® 5 Hole Shells
K082924	DYNASTY® BIOFOAM® Shells

The subject DYNASTY® Acetabular System with Ceramic is indicated to be paired with the following femoral components summarized in Table 2.

Table 2. Compatible Femoral Components, Including 510(k) Information. All femoral stems were cleared for use with Biolox Delta heads in K130376, except K130984.

510(k)	Device Name
K003016	PRO-FEMUR R
K012091	PRO-FEMUR
K021346	STEM HIP REPLACEMENT SYSTEM
K041114	PROFEMUR TAPERED HIP STEM
K041586	PROFEMUR S HIP STEM
K051995	PROFEMUR RENAISSANCE HIP STEM
K052915	PROFEMUR XTR HIP STEM
K053588	PROFEMUR LX HIP STEM
K060358	PROFEMUR TL HIP STEM
K080663	PROFEMUR LX REVISION 5/8 COATED HIP STEM
K081090	PROFEMUR LX 5/8 COATED HIP STEM
K091423 K100866	PROFEMUR HIP SYSTEM MODULAR NECKS
K110399	GLADIATOR PLASMA CLASSIC HIP STEM
K111698	PROFEMUR(R) E CEMENTLESS HIP STEM
K111699	PROFEMUR(R) Z TITANIUM PLASMA SPRAYED HIP STEM
K111910	GLADIATOR HIP STEM
K112080	PRESERVE HIP STEM
K112150	PROFEMUR GLADIATOR HA HIP STEM
K121221	PROFEMUR Z REVISION HIP STEM
K123434	PROFEMUR Z CLASSIC STEM
K123688	PROFEMUR TL CLASSIC STEM
K130984	PROFEMUR RENAISSANCE CLASSIC STEM

The design features of the subject femoral head devices are substantially equivalent to those of the predicate DYNASTY® Acetabular system devices cleared under K130376. The design features of the subject acetabular liner and shell devices are substantially equivalent to those of the predicate LINEAGE® Acetabular system devices cleared under K052026 and K002149. The indications of the subject device are identical to the predicate. Specific warnings are added in the package insert. The fundamental scientific technology of the modified devices has not changed relative to the predicate

devices. Validation of sterilization residuals by ethylene oxide was conducted on devices cleared in K893685 and K002149; this validation was submitted in K130376, is applicable to the subject devices and is included again in this notification. The safety and effectiveness of the DYNASTY® Acetabular System with Ceramic is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

D. Nonclinical Testing

The subject DYNASTY® Acetabular System with Ceramic was evaluated mechanically and tribologically. The mechanical testing on the subject and predicate devices was performed on wrought Cobalt Chrome modular neck spigots cleared under K091423 and K100866. The subject size 28mm ceramic head was used as a worst case in burst, post-fatigue burst, rotational stability, and pull off force testing. Wear testing compared the subject size 28mm femoral heads to the K130376 DYNASTY® Acetabular System. Range of motion evaluation compared the subject system to the predicate K052026 in three planes.

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Conclusion

The design features of the subject devices are substantially equivalent to the predicate devices. The instrument list and materials remain identical to those cleared under K122382 and K130376. The safety and effectiveness of the DYNASTY® Acetabular System with Ceramic is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

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

April 3, 2014

MicroPort Orthopedics, Inc.
Max Mortensen, Ph.D.
VP Global Quality Systems, Regulatory and Clinical Affairs,
Reimbursement and Market Access
5677 Airline Road
Arlington, Tennessee 38002

Re: K140043
Trade/Device Name: Dynasty Acetabular System
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 17, 2013
Received: January 8, 2014

Dear Dr. Mortensen:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140043

Device Name
Dynasty Acetabular System

Indications for Use *(Describe)*

The DYNASTY® Acetabular System is intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
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Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty. Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.

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)*

Elizabeth D Frank -S

Division of Orthopedic Devices

REGULATORY COMPLIANCE ASSOCIATES® INC.

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See Attached for K#s.

FDA CDRH DMC

FEB 28 2014

Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 27, 2014

TO: 510(k) Staff
CDRH Document Control Center

CC: Max Mortenson, MicroPort Orthopedics, VP Global Operations and Product Support

Re: Bundled Submission
eCopy Hold dated 2/21/2014 – 2/25/2014

Dear 510(k) Staff:

Please find enclosed a replacement eCopy for the bundled submission in regard to FDA's eCopy Hold requests for additional information dated February 21, 2014 through February 25, 2014.

Enclosed is a reference copy of the January 9, 2014 Transfer of Ownership of 510(k)s Letter. The original document was received by FDA on February 19, 2014.

The electronic copy is an exact duplicate of the previously provided paper original.

Please contact me if you have any questions or concerns.

Sincerely,

Darla C. Chew

Darla C. Chew
Regulatory Affairs
Regulatory Compliance Associates, Inc.
214.592.7131 cell
d.chew@rcainc.com
www.rcainc.com

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REGULATORY COMPLIANCE ASSOCIATES® INC.

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Food and Drug Administration
Center for Devices and Radiological Health
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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
FEB 28 2014
Received

February 27, 2014

TO: 510(k) Staff
CDRH Document Control Center

CC: Max Mortenson, MicroPort Orthopedics, VP Global Operations and Product Support

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eCopy Hold dated 2/21/2014 – 2/25/2014

Dear 510(k) Staff:

Please find enclosed a replacement eCopy for the bundled submission in regard to FDA's eCopy Hold requests for additional information dated February 21, 2014 through February 25, 2014.

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The electronic copy is an exact duplicate of the previously provided paper original.

Please contact me if you have any questions or concerns.

Sincerely,

Darla C. Chew

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Regulatory Affairs
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MicroPort Orthopedics

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See Attached for K#'s.

January 9, 2014

FDA/CDRH/DCC
FEB 19 2014
RECEIVED

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

ATTN: Document Control
RE: Transfer of Ownership of 510(k)s

Dear Sir or Madam:

By copy of this letter, please be advised that Wright Medical Technology Inc. (WMT) Establishment Registration number: 1043534 has officially transferred ownership of all 510(k)s related to its Hip and Knee product codes pursuant to a recent sale of company assets.

Accordingly, effective January 9, 2014 WMT transferred all rights, title and interest in the 510(k)s listed in Appendix I to MicroPort Orthopedics Inc. at 5677 Airline Road, Arlington, Tennessee 38002 (Establishment Registration 3010536692).

It is understood that transfer of 510(k) rights alone does not require submission of a new 510(k) under 21 CFR 807.85(b)(2) and consequently, FDA cannot change the name of the original 510(k) submitter in its database

Therefore, information showing the transfer of the 510(k) s and their current ownership will be maintained in each company's files for review by an FDA investigator. MicroPort Orthopedics, Establishment Registration number 3010536692, will submit an official Device Listing in their name to distribute the referenced 510(k) products. If changes are made that require a PMA supplement or affect the conditions of approval, MicroPort will submit an appropriate PMA supplement and obtain written FDA approval before marketing the device.

Going forward, the official correspondent for questions relating the 510(k) s referenced in Appendix I is:

Authorized Contact

Max Mortensen Ph.D.
MicroPort Orthopedics Inc.
VP Global Quality Systems, Regulatory and Clinical Affairs,
Reimbursement and Market Access
5677 Airline Road
Arlington, TN 38002
Cell: 901-485-1102
Office: 901-290-5898
Email: max.mortensen@ortho.microport.com

Signed for and on behalf of MicroPort Orthopedics Inc. and Wright Medical Technology, Inc. by:

Name: Ted Davis Sign:

Title: Chief Executive Officer

MicroPort Orthopedics Inc.
5677 Airline Road
Arlington, TN 38002

Name: Pascal Girin Sign:

Title: EVP & Chief Operating Officer

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Appendix

510(K) NUMBER	APPROVAL DATE	PRODUCT	510(k) Applicant
K873857/A1	12/1/1987	WHITESIDE ORTHOLOC REVISION HIP STEM PROSTHESIS	DOW CORNING WRIGHT
K864626/A1	12/15/1986	CANCELLOUS BONE SCREW	DOW CORNING WRIGHT
K864627/A1	2/4/1987	WHITESIDE ORTHOLOC II METAL BACKED PATELLA	DOW CORNING WRIGHT
K870174/A1	2/6/1987	MCCUTCHEN FEMORAL HIP PROSTHESIS	DOW CORNING WRIGHT
K902538/A1	7/6/1990	WHITESIDE ORTHOLOC MODULAR TIBIAL AUGMENTATION	DOW CORNING WRIGHT
K905076/A1	2/13/1991	WHITESIDE ORTHOLOC MODULAR TIBIAL CONSTRAIN.INSERT	DOW CORNING WRIGHT
K910596/A1	5/29/1991	DCW MODULAR DISTAL FEMORAL SYSTEM	DOW CORNING WRIGHT
K911595/A1	7/12/1991	INFINITY(TM) POROUS-COATED TROCHANTERIC MODULE	DOW CORNING WRIGHT
K922159/A1	10/15/1993	INFINITY POROUS-COATED TROCHANTERIC MODULE	WRIGHT MEDICAL TECHNOLOGY INC.
K933871/A3	2/23/1994	BRIDGE(TM) HIP SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K933570/A2	3/7/1994	RESOLUTION(TM) HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K933281/A5	6/7/1994	S.O.S. PROXIMAL FEMUR	WRIGHT MEDICAL TECHNOLOGY INC.
K933289/A2	8/25/1994	THICK TIBIAL INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K933290/A4	9/1/1994	ORTHOLOC ADVANTIM	WRIGHT MEDICAL TECHNOLOGY INC.
K934620/A6	9/1/1994	ORTHOLOC ADVANTIM FIXED STEM NON-POROUS TIBIAL BASE	WRIGHT MEDICAL TECHNOLOGY INC.
K942115/A2	9/28/1994	INFINITY REVISION HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K940235/A8	10/5/1994	ORTHOLOC ADVANTIM PS LSI TIBIAL INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K944845/A2	12/15/1994	ORTHOLOC ADVANTIM MODULAR FEMORAL AUGMENT COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K941755/A1	1/17/1995	ORTHOLOC ADVANTIM LSI POSTERIOR STABLIZED ALL POLYTHYLENE TIBIAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.

K945087/A4	3/17/1995	ORTHOLOC ADVANTIM POROUS COATED TIBIAL BASE	WRIGHT MEDICAL TECHNOLOGY INC.
K944856/A2	5/16/1995	ORTHOMET ACETABULAR ROOF REINFORCEMENT RING	WRIGHT MEDICAL TECHNOLOGY INC.
K950418/A1	6/15/1995	ALPHA POROUS COATED FEMORAL COMPONENT (SUBJECT TO WMTI MARKETING APPROVAL)	WRIGHT MEDICAL TECHNOLOGY INC.
K952640/A2	7/31/1995	CANNULATED PLUS HIP SCREW	WRIGHT MEDICAL TECHNOLOGY INC.
K953025/A1	9/8/1995	SLT 28MM XXL FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
K944689/A2	10/20/1995	ZIRCONIA CERAMIC FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
K954262/A2	11/3/1995	NEXUS II FEMORAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K951139/A1	11/22/1995	ALPHA LONG STEM FEMORAL COMPONENT (SUBJECT TO WMTI MARKETING APPROVAL)	WRIGHT MEDICAL TECHNOLOGY INC.
K954288/A6	11/30/1995	EXTEND HIP SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K945774/A2	12/28/1995	BETA FEMORAL HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K955229/A3	1/18/1996	WRIGHT MEDICAL TECHNOLOGY SAWBLADES	WRIGHT MEDICAL TECHNOLOGY INC.
K953439/A1	1/30/1996	ULTRACK TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K955837/A1	3/4/1996	CANNULATED PLUS HIP SCREW (STERILE)	WRIGHT MEDICAL TECHNOLOGY INC.
K960617/A3	5/8/1996	ADVANCE TIBIAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K961900/A1	7/25/1996	TIBIAL TRAY PLUG A PRODUCT LINE ADDITION TO THE AXIOM TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K962267/A3	9/10/1996	PERFECTA PS REVISION STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K955553/A1	10/24/1996	PERFECTA REVISION HIP SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K964218/A2	1/8/1997	PERFECTA PLASMA SPRAY HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K964249/A1	1/14/1997	BRIDGE LONG STEM FEMORAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K971135/A2	6/5/1997	MAGELLAN INTRAMEDULLARY FEMORAL NAIL SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.

K971429/A1	7/9/1997	INTERSEAL ACETABULAR SCREW HOLE PLUG	WRIGHT MEDICAL TECHNOLOGY INC.
K972626/A1	9/29/1997	ADVANCE KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K971056/A1	10/3/1997	MAGELLAN MAGNETIC DISTAL TARGETING SYSTEM(PROPOSED NAME) PRODUCT LINE EXTENSION	WRIGHT MEDICAL TECHNOLOGY INC.
K972641/A3	10/9/1997	DUAL OFFSET PERFECTA IMC HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K972770/A3	10/21/1997	ADVANCE ULTRA-CONGRUENT TIBIAL INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K973296/A4	11/24/1997	EXTEND HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K973524/A4	12/12/1997	ADVANCE MODULAR TIBIAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K974328/A1	1/30/1998	ADVANCE TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K982390/A1	9/14/1998	CONCISE COMPRESSION HIP SCREW SYSTEM (STERILE)	WRIGHT MEDICAL TECHNOLOGY INC.
K990030/A2	2/3/1999	ADVANCED REVISION PRODUCT LINE EXTENSION	WRIGHT MEDICAL TECHNOLOGY INC.
K991123/A2	6/1/1999	PERFECTA RS LATERALIZED HIP STEM BRIDGE HIP SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K993371/A2	12/20/1999	SADDLE SHAPED PATELLA	WRIGHT MEDICAL TECHNOLOGY INC.
K002149/A1	8/31/2000	LINEAGE ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K003016/A1	12/13/2000	PRO-FEMUR R	WRIGHT MEDICAL TECHNOLOGY INC.
K004032/A2	2/15/2001	PERFECTA AND EXTEND	WRIGHT MEDICAL TECHNOLOGY INC.
K004043/A2	7/13/2001	METAL TRANSCEND ARTICULATION SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K012091/A2	10/3/2001	PRO-FEMUR	WRIGHT MEDICAL TECHNOLOGY INC.
K012591/A1	11/2/2001	ADVANCE UNICONDYLAR KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K013035/A1	12/7/2001	GUARDIAN LIMB SALVAGE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K014171/A2	3/15/2002	ADVANCE UNICONDYLAR KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K021349/A1	7/1/2002	METAL TRANSCEND ARTICULATION SYSTEM	WRIGHT MEDICAL

		(LARGER SIZES)	TECHNOLOGY INC.
K021346/A1	7/2/2002	STEM HIP REPLACEMENT SYSTEM MODEL PHA002XX	WRIGHT MEDICAL TECHNOLOGY INC.
K021489/A4	12/4/2002	REPIPHYSIS LIMB SALVAGE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K030193/A2	2/20/2003	ADVANCE LESS CONFORMING TIBIAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K031963/A1	10/31/2003	CONSERVE PLUS SPIKED ACETABULAR SHELLS AND CONSERVE TOTAL 56MM FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
K033890/A1	1/15/2004	ADVANCE DOUBLE HIGH INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K034028/A1	3/11/2004	ATH FEMORAL STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K041114/A2	5/28/2004	PROFEMUR TAPERED HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K041425/A2	6/25/2004	CONSERVE PLUS REVISION SHELL AND CONSERVE PLUS THICK SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K041586/A1	7/9/2004	PROFEMUR S HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K031402/A3	11/22/2004	PERFECTA FEMORAL STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K042530/A1	12/17/2004	CONSERVE PLUS HA ACETABULAR SHELLS	WRIGHT MEDICAL TECHNOLOGY INC.
K043083/A1	4/18/2005	ADVANCE HA COATED SPIKED TIBIAL BASE AND ADVANCE HA COATED MODULAR KEEL	WRIGHT MEDICAL TECHNOLOGY INC.
K043073/A1	5/4/2005	PROCOTYL-E ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K051348/A3	8/19/2005	CONSERVE TOTAL FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
K051995/A1	8/22/2005	PROFEMUR RENAISSANCE HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K043099/A1	9/29/2005	LINEAGE HA ACETABULAR SHELLS	WRIGHT MEDICAL TECHNOLOGY INC.
K052026/A2	12/5/2005	LINEAGE A-CLASS POLY LINER	WRIGHT MEDICAL TECHNOLOGY INC.
K053588/A1	1/13/2006	PROFEMUR LX HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K052915/A2	1/27/2006	PROFEMUR XTR HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K060356/A1	4/18/2006	CONSERVE PLUS QUADRAFIX ACETABULAR SHELL	WRIGHT MEDICAL TECHNOLOGY INC.

K060358/A1	5/10/2006	PROFEMUR TL HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K061547/A1	7/3/2006	DYNASTY ACETABULAR SHELL; DYNASTY A-CLASS POLY ACETABULAR LINER	WRIGHT MEDICAL TECHNOLOGY INC.
K061223/A1	8/18/2006	ADVANCE TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K062693/A1	9/29/2006	GLADIATOR BIPOLAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K062960/A3	12/1/2006	CONSERVE FEMORAL RESURFACING COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K061844/A1	12/6/2006	DYNASTY ACETABULAR SHELL AND COCR ACETABULAR LINER	WRIGHT MEDICAL TECHNOLOGY INC.
K063731/A1	3/2/2007	ADVANCE STATURE FEMORAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K063128/A1	3/21/2007	ADVANCE SPIKED POROUS TIBIAL BASE	WRIGHT MEDICAL TECHNOLOGY INC.
K070785/A1	7/11/2007	DYNASTY ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K072367/A1	1/9/2008	REPIPHYSIS LIMB SALVAGE PROXIMAL FEMUR AND TOTAL FEMUR	WRIGHT MEDICAL TECHNOLOGY INC.
K072656/A1	2/6/2008	DYNASTY CERAMIC FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
K080663/A1	4/8/2008	PROFEMUR LX REVISION 5/8 COATED HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K081090/A1	5/15/2008	PROFEMUR LX 5/8 COATED HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K082673/A1	12/12/2008	CONSERVE PRESSFIT FEMORAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K081479/A1	2/20/2009	ADVANCE A-CLASS TIBIAL INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K082924/A1	3/6/2009	DYNASTY POROUS ACETABULAR SHELL DYNASTY POLYETHYLENE ACETABULAR LINER DYNASTY METAL ACETABULAR LINER	WRIGHT MEDICAL TECHNOLOGY INC.
K092201/A1	8/20/2009	ADVANCE 913 MEDIAL PIVOT TIBIAL INSERT ADVANCE 913 MEDIAL PIVOT TIBIAL BASE	WRIGHT MEDICAL TECHNOLOGY INC.
K091423/A1	8/25/2009	PROFEMUR HIP SYSTEM MODULAR NECKS	WRIGHT MEDICAL TECHNOLOGY INC.
K093552/A1	3/4/2010	EVOLUTION MP TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K100866/A1	4/28/2010	PROFEMUR HIP SYSTEM MODULAR NECKS	WRIGHT MEDICAL TECHNOLOGY INC.

K093405/A2	5/25/2010	PROPHECY PRE-OPERATIVE NAVIGATION ALIGNMENT GUIDES	WRIGHT MEDICAL TECHNOLOGY INC.
K100973/A1	8/10/2010	EVOLUTION UNICONDYLAR KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K102565/A1	12/22/2010	ANTERIOR APPROACH HIP SURGERY INSTRUMENTS	WRIGHT MEDICAL TECHNOLOGY INC.
K102380/A1	1/7/2011	EVOLUTION MP TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K110029/A1	4/19/2011	CONSERVE BIO FOAM SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K110399/A1	5/10/2011	GLADIATOR PLASMA CLASSIC HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K111698/A1	8/19/2011	PROFEMUR(R) E CEMENTLESS HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K111699/A1	8/19/2011	PROFEMUR(R) Z TITANIUM PLASMA SPRAYED HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K111910/A1	10/14/2011	GLADIATOR HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K103598/A1	10/17/2011	PROPHECY PRE-OPERATIVE NAVIGATION ALIGNMENT GUIDES	WRIGHT MEDICAL TECHNOLOGY INC.
K113019/A1	11/10/2011	PROFEMUR XM WINGLESS DISTAL CENTRALIZER PERFECTA DISTAL CENTRALIZER	WRIGHT MEDICAL TECHNOLOGY INC.
K112150/A1	11/23/2011	PROFEMUR GLADIATOR HA HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K113325/A1	12/9/2011	EVOLUTION MP ADAPTIVE CS INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K112080/A2	12/28/2011	PRESERVE HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K113322/A1	2/3/2012	CONSERVE THIN SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K121544/A1	7/30/2012	DYNASTY BIOFOAM SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K121221/A1	8/9/2012	PROFEMUR Z REVISION HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K122778/A1	10/11/2012	PROFEMUR Z REVISION HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K122382/A1	10/22/2012	DYNASTY BIOFOAM SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K123434/A1	2/5/2013	PROFEMUR Z CLASSIC STEMS	WRIGHT MEDICAL TECHNOLOGY INC.
K123688/A1	2/8/2013	PROFEMUR TL CLASSIC HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.

K122218/A1	3/21/2013	ADVANCE TOTAL KNEE SYSTEM-PATELLA	WRIGHT MEDICAL TECHNOLOGY INC.
K130167/A1	4/19/2013	PROFEMUR XM DISTAL CENTRALIZER	WRIGHT MEDICAL TECHNOLOGY INC.
K130984/A1	5/24/2013	PROFEMUR RENAISSANCE CLASSIC HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K130376/A1	7/3/2013	DYNASTY ACETABULAR SYSTEM WITH CERAMIC	WRIGHT MEDICAL TECHNOLOGY INC.
K131679/A1	10/23/2013	EVOLUTION MP ADAPTIVE PS INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K133426/A1	UNDER REVIEW	DYNASTY ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K140043/A1	UNDER REVIEW	DYNASTY ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.

MicroPort Orthopedics

WRIGHT
FOCUSED EXCELLENCE

January 9, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

ATTN: Document Control
RE: Transfer of Ownership of 510(k)s

Dear Sir or Madam:

By copy of this letter, please be advised that Wright Medical Technology Inc. (WMT) Establishment Registration number: 1043534 has officially transferred ownership of all 510(k)s related to its Hip and Knee product codes pursuant to a recent sale of company assets.

Accordingly, effective January 9, 2014 WMT transferred all rights, title and interest in the 510(k)s listed in Appendix I to MicroPort Orthopedics Inc. at 5677 Airline Road, Arlington, Tennessee 38002 (Establishment Registration 3010536692).

It is understood that transfer of 510(k) rights alone does not require submission of a new 510(k) under 21 CFR 807.85(b)(2) and consequently, FDA cannot change the name of the original 510(k) submitter in its database

Therefore, information showing the transfer of the 510(k) s and their current ownership will be maintained in each company's files for review by an FDA investigator. MicroPort Orthopedics, Establishment Registration number 3010536692, will submit an official Device Listing in their name to distribute the referenced 510(k) products. If changes are made that require a PMA supplement or affect the conditions of approval, MicroPort will submit an appropriate PMA supplement and obtain written FDA approval before marketing the device.

Going forward, the official correspondent for questions relating the 510(k) s referenced in Appendix I is:

Authorized Contact

Max Mortensen Ph.D.
MicroPort Orthopedics Inc.
VP Global Quality Systems, Regulatory and Clinical Affairs,
Reimbursement and Market Access
5677 Airline Road
Arlington, TN 38002
Cell: 901-485-1102
Office: 901-290-5898
Email: max.mortensen@ortho.microport.com

Signed for and on behalf of MicroPort Orthopedics Inc. and Wright Medical Technology, Inc. by:

Name: Ted Davis Sign: _____

Title: Chief Executive Officer

MicroPort Orthopedics Inc.
5677 Airline Road
Arlington, TN 38002

Name: Pascal Girin Sign: _____

Title: EVP & Chief Operating Officer

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Appendix

510(K) NUMBER	APPROVAL DATE	PRODUCT	510(k) Applicant
K873857	12/1/1987	WHITESIDE ORTHOLOC REVISION HIP STEM PROSTHESIS	DOW CORNING WRIGHT
K864626	12/15/1986	CANCELLOUS BONE SCREW	DOW CORNING WRIGHT
K864627	2/4/1987	WHITESIDE ORTHOLOC II METAL BACKED PATELLA	DOW CORNING WRIGHT
K870174	2/6/1987	MCCUTCHEN FEMORAL HIP PROSTHESIS	DOW CORNING WRIGHT
K902538	7/6/1990	WHITESIDE ORTHOLOC MODULAR TIBIAL AUGMENTATION	DOW CORNING WRIGHT
K905076	2/13/1991	WHITESIDE ORTHOLOC MODULAR TIBIAL CONSTRAIN.INSERT	DOW CORNING WRIGHT
K910596	5/29/1991	DCW MODULAR DISTAL FEMORAL SYSTEM	DOW CORNING WRIGHT
K911595	7/12/1991	INFINITY(TM) POROUS-COATED TROCHANTERIC MODULE	DOW CORNING WRIGHT
K922159	10/15/1993	INFINITY POROUS-COATED TROCHANTERIC MODULE	WRIGHT MEDICAL TECHNOLOGY INC.
K933871	2/23/1994	BRIDGE(TM) HIP SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K933570	3/7/1994	RESOLUTION(TM) HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K933281	6/7/1994	S.O.S. PROXIMAL FEMUR	WRIGHT MEDICAL TECHNOLOGY INC.
K933289	8/25/1994	THICK TIBIAL INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K933290	9/1/1994	ORTHOLOC ADVANTIM	WRIGHT MEDICAL TECHNOLOGY INC.
K934620	9/1/1994	ORTHOLOC ADVANTIM FIXED STEM NON-POROUS TIBIAL BASE	WRIGHT MEDICAL TECHNOLOGY INC.
K942115	9/28/1994	INFINITY REVISION HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K940235	10/5/1994	ORTHOLOC ADVANTIM PS LSI TIBIAL INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K944845	12/15/1994	ORTHOLOC ADVANTIM MODULAR FEMORAL AUGMENT COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K941755	1/17/1995	ORTHOLOC ADVANTIM LSI POSTERIOR STABLIZED ALL POLYTHYLENE TIBIAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.

K945087	3/17/1995	ORTHOLOC ADVANTIM POROUS COATED TIBIAL BASE	WRIGHT MEDICAL TECHNOLOGY INC.
K944856	5/16/1995	ORTHOMET ACETABULAR ROOF REINFORCEMENT RING	WRIGHT MEDICAL TECHNOLOGY INC.
K950418	6/15/1995	ALPHA POROUS COATED FEMORAL COMPONENT (SUBJECT TO WMTI MARKETING APPROVAL)	WRIGHT MEDICAL TECHNOLOGY INC.
K952640	7/31/1995	CANNULATED PLUS HIP SCREW	WRIGHT MEDICAL TECHNOLOGY INC.
K953025	9/8/1995	SLT 28MM XXL FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
K944689	10/20/1995	ZIRCONIA CERAMIC FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
K954262	11/3/1995	NEXUS II FEMORAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K951139	11/22/1995	ALPHA LONG STEM FEMORAL COMPONENT (SUBJECT TO WMTI MARKETING APPROVAL)	WRIGHT MEDICAL TECHNOLOGY INC.
K954288	11/30/1995	EXTEND HIP SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K945774	12/28/1995	BETA FEMORAL HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K955229	1/18/1996	WRIGHT MEDICAL TECHNOLOGY SAWBLADES	WRIGHT MEDICAL TECHNOLOGY INC.
K953439	1/30/1996	ULTRACK TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K955837	3/4/1996	CANNULATED PLUS HIP SCREW (STERILE)	WRIGHT MEDICAL TECHNOLOGY INC.
K960617	5/8/1996	ADVANCE TIBIAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K961900	7/25/1996	TIBIAL TRAY PLUG A PRODUCT LINE ADDITION TO THE AXIOM TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K962267	9/10/1996	PERFECTA PS REVISION STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K955553	10/24/1996	PERFECTA REVISION HIP SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K964218	1/8/1997	PERFECTA PLASMA SPRAY HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K964249	1/14/1997	BRIDGE LONG STEM FEMORAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K971135	6/5/1997	MAGELLAN INTRAMEDULLARY FEMORAL NAIL SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.

K971429	7/9/1997	INTERSEAL ACETABULAR SCREW HOLE PLUG	WRIGHT MEDICAL TECHNOLOGY INC.
K972626	9/29/1997	ADVANCE KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K971056	10/3/1997	MAGELLAN MAGNETIC DISTAL TARGETING SYSTEM(PROPOSED NAME) PRODUCT LINE EXTENSION	WRIGHT MEDICAL TECHNOLOGY INC.
K972641	10/9/1997	DUAL OFFSET PERFECTA IMC HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K972770	10/21/1997	ADVANCE ULTRA-CONGRUENT TIBIAL INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K973296	11/24/1997	EXTEND HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K973524	12/12/1997	ADVANCE MODULAR TIBIAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K974328	1/30/1998	ADVANCE TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K982390	9/14/1998	CONCISE COMPRESSION HIP SCREW SYSTEM (STERILE)	WRIGHT MEDICAL TECHNOLOGY INC.
K990030	2/3/1999	ADVANCED REVISION PRODUCT LINE EXTENSION	WRIGHT MEDICAL TECHNOLOGY INC.
K991123	6/1/1999	PERFECTA RS LATERALIZED HIP STEM BRIDGE HIP SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K993371	12/20/1999	SADDLE SHAPED PATELLA	WRIGHT MEDICAL TECHNOLOGY INC.
K002149	8/31/2000	LINEAGE ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K003016	12/13/2000	PRO-FEMUR R	WRIGHT MEDICAL TECHNOLOGY INC.
K004032	2/15/2001	PERFECTA AND EXTEND	WRIGHT MEDICAL TECHNOLOGY INC.
K004043	7/13/2001	METAL TRANSCEND ARTICULATION SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K012091	10/3/2001	PRO-FEMUR	WRIGHT MEDICAL TECHNOLOGY INC.
K012591	11/2/2001	ADVANCE UNICONDYLAR KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K013035	12/7/2001	GUARDIAN LIMB SALVAGE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K014171	3/15/2002	ADVANCE UNICONDYLAR KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K021349	7/1/2002	METAL TRANSCEND ARTICULATION SYSTEM	WRIGHT MEDICAL

		(LARGER SIZES)	TECHNOLOGY INC.
K021346	7/2/2002	STEM HIP REPLACEMENT SYSTEM MODEL PHA002XX	WRIGHT MEDICAL TECHNOLOGY INC.
K021489	12/4/2002	REPIPHYSIS LIMB SALVAGE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K030193	2/20/2003	ADVANCE LESS CONFORMING TIBIAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K031963	10/31/2003	CONSERVE PLUS SPIKED ACETABULAR SHELLS AND CONSERVE TOTAL 56MM FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
K033890	1/15/2004	ADVANCE DOUBLE HIGH INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K034028	3/11/2004	ATH FEMORAL STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K041114	5/28/2004	PROFEMUR TAPERED HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K041425	6/25/2004	CONSERVE PLUS REVISION SHELL AND CONSERVE PLUS THICK SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K041586	7/9/2004	PROFEMUR S HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K031402	11/22/2004	PERFECTA FEMORAL STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K042530	12/17/2004	CONSERVE PLUS HA ACETABULAR SHELLS	WRIGHT MEDICAL TECHNOLOGY INC.
K043083	4/18/2005	ADVANCE HA COATED SPIKED TIBIAL BASE AND ADVANCE HA COATED MODULAR KEEL	WRIGHT MEDICAL TECHNOLOGY INC.
K043073	5/4/2005	PROCOTYL-E ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K051348	8/19/2005	CONSERVE TOTAL FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
K051995	8/22/2005	PROFEMUR RENAISSANCE HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K043099	9/29/2005	LINEAGE HA ACETABULAR SHELLS	WRIGHT MEDICAL TECHNOLOGY INC.
K052026	12/5/2005	LINEAGE A-CLASS POLY LINER	WRIGHT MEDICAL TECHNOLOGY INC.
K053588	1/13/2006	PROFEMUR LX HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K052915	1/27/2006	PROFEMUR XTR HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K060356	4/18/2006	CONSERVE PLUS QUADRAFIX ACETABULAR SHELL	WRIGHT MEDICAL TECHNOLOGY INC.

K060358	5/10/2006	PROFEMUR TL HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K061547	7/3/2006	DYNASTY ACETABULAR SHELL; DYNASTY A-CLASS POLY ACETABULAR LINER	WRIGHT MEDICAL TECHNOLOGY INC.
K061223	8/18/2006	ADVANCE TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K062693	9/29/2006	GLADIATOR BIPOLAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K062960	12/1/2006	CONSERVE FEMORAL RESURFACING COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K061844	12/6/2006	DYNASTY ACETABULAR SHELL AND COCR ACETABULAR LINER	WRIGHT MEDICAL TECHNOLOGY INC.
K063731	3/2/2007	ADVANCE STATURE FEMORAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K063128	3/21/2007	ADVANCE SPIKED POROUS TIBIAL BASE	WRIGHT MEDICAL TECHNOLOGY INC.
K070785	7/11/2007	DYNASTY ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K072367	1/9/2008	REPIPHYSIS LIMB SALVAGE PROXIMAL FEMUR AND TOTAL FEMUR	WRIGHT MEDICAL TECHNOLOGY INC.
K072656	2/6/2008	DYNASTY CERAMIC FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
K080663	4/8/2008	PROFEMUR LX REVISION 5/8 COATED HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K081090	5/15/2008	PROFEMUR LX 5/8 COATED HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K082673	12/12/2008	CONSERVE PRESSFIT FEMORAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K081479	2/20/2009	ADVANCE A-CLASS TIBIAL INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K082924	3/6/2009	DYNASTY POROUS ACETABULAR SHELL DYNASTY POLYETHYLENE ACETABULAR LINER DYNASTY METAL ACETABULAR LINER	WRIGHT MEDICAL TECHNOLOGY INC.
K092201	8/20/2009	ADVANCE 913 MEDIAL PIVOT TIBIAL INSERT ADVANCE 913 MEDIAL PIVOT TIBIAL BASE	WRIGHT MEDICAL TECHNOLOGY INC.
K091423	8/25/2009	PROFEMUR HIP SYSTEM MODULAR NECKS	WRIGHT MEDICAL TECHNOLOGY INC.
K093552	3/4/2010	EVOLUTION MP TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K100866	4/28/2010	PROFEMUR HIP SYSTEM MODULAR NECKS	WRIGHT MEDICAL TECHNOLOGY INC.

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K102380	1/7/2011	EVOLUTION MP TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K110029	4/19/2011	CONSERVE BIO FOAM SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K110399	5/10/2011	GLADIATOR PLASMA CLASSIC HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K111698	8/19/2011	PROFEMUR(R) E CEMENTLESS HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K111699	8/19/2011	PROFEMUR(R) Z TITANIUM PLASMA SPRAYED HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K111910	10/14/2011	GLADIATOR HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K103598	10/17/2011	PROPHECY PRE-OPERATIVE NAVIGATION ALIGNMENT GUIDES	WRIGHT MEDICAL TECHNOLOGY INC.
K113019	11/10/2011	PROFEMUR XM WINGLESS DISTAL CENTRALIZER PERFECTA DISTAL CENTRALIZER	WRIGHT MEDICAL TECHNOLOGY INC.
K112150	11/23/2011	PROFEMUR GLADIATOR HA HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K113325	12/9/2011	EVOLUTION MP ADAPTIVE CS INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K112080	12/28/2011	PRESERVE HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K113322	2/3/2012	CONSERVE THIN SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K121544	7/30/2012	DYNASTY BIOFOAM SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K121221	8/9/2012	PROFEMUR Z REVISION HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K122778	10/11/2012	PROFEMUR Z REVISION HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K122382	10/22/2012	DYNASTY BIOFOAM SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K123434	2/5/2013	PROFEMUR Z CLASSIC STEMS	WRIGHT MEDICAL TECHNOLOGY INC.
K123688	2/8/2013	PROFEMUR TL CLASSIC HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.

K122218	3/21/2013	ADVANCE TOTAL KNEE SYSTEM-PATELLA	WRIGHT MEDICAL TECHNOLOGY INC.
K130167	4/19/2013	PROFEMUR XM DISTAL CENTRALIZER	WRIGHT MEDICAL TECHNOLOGY INC.
K130984	5/24/2013	PROFEMUR RENAISSANCE CLASSIC HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K130376	7/3/2013	DYNASTY ACETABULAR SYSTEM WITH CERAMIC	WRIGHT MEDICAL TECHNOLOGY INC.
K131679	10/23/2013	EVOLUTION MP ADAPTIVE PS INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K133426	UNDER REVIEW	DYNASTY ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K140043	UNDER REVIEW	DYNASTY ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date:

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K140043 / A001

To: Division Director: OR / DOD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: _____

Date: _____

REGULATORY COMPLIANCE ASSOCIATES® INC.

WELLNESS FOR BUSINESS®

See Attached for K#s.

FDA CDRH DMC

FEB 28 2014

Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 27, 2014

TO: 510(k) Staff
CDRH Document Control Center

CC: Max Mortenson, MicroPort Orthopedics, VP Global Operations and Product Support

Re: Bundled Submission
eCopy Hold dated 2/21/2014 – 2/25/2014

Dear 510(k) Staff:

Please find enclosed a replacement eCopy for the bundled submission in regard to FDA's eCopy Hold requests for additional information dated February 21, 2014 through February 25, 2014.

Enclosed is a reference copy of the January 9, 2014 Transfer of Ownership of 510(k)s Letter. The original document was received by FDA on February 19, 2014.

The electronic copy is an exact duplicate of the previously provided paper original.

Please contact me if you have any questions or concerns.

Sincerely,

Darla C. Chew

Darla C. Chew
Regulatory Affairs
Regulatory Compliance Associates, Inc.
214.592.7131 cell
d.chew@rcainc.com
www.rcainc.com

2

MicroPort Orthopedics

K873857/A1

WRIGHT
FOCUSED EXCELLENCE

January 9, 2014

FDA CDRH DMC
FEB 19 2014
Received

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

ATTN: Document Control
RE: Transfer of Ownership of 510(k)s

Dear Sir or Madam:

By copy of this letter, please be advised that Wright Medical Technology Inc. (WMT) Establishment Registration number: 1043534 has officially transferred ownership of all 510(k)s related to its Hip and Knee product codes pursuant to a recent sale of company assets.

Accordingly, effective January 9, 2014 WMT transferred all rights, title and interest in the 510(k)s listed in Appendix I to MicroPort Orthopedics Inc. at 5677 Airline Road, Arlington, Tennessee 38002 (Establishment Registration 3010536692).

It is understood that transfer of 510(k) rights alone does not require submission of a new 510(k) under 21 CFR 807.85(b)(2) and consequently, FDA cannot change the name of the original 510(k) submitter in its database

Therefore, information showing the transfer of the 510(k) s and their current ownership will be maintained in each company's files for review by an FDA investigator. MicroPort Orthopedics, Establishment Registration number 3010536692, will submit an official Device Listing in their name to distribute the referenced 510(k) products. If changes are made that require a PMA supplement or affect the conditions of approval, MicroPort will submit an appropriate PMA supplement and obtain written FDA approval before marketing the device.

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Going forward, the official correspondent for questions relating the 510(k) s referenced in Appendix I is:

Authorized Contact

Max Mortensen Ph.D.
MicroPort Orthopedics Inc.
VP Global Quality Systems, Regulatory and Clinical Affairs,
Reimbursement and Market Access
5677 Airline Road
Arlington, TN 38002
Cell: 901-485-1102
Office: 901-290-5898
Email: max.mortensen@ortho.microport.com

Signed for and on behalf of MicroPort Orthopedics Inc. and Wright Medical Technology, Inc. by:

Name: Ted Davis Sign:

Title: Chief Executive Officer

MicroPort Orthopedics Inc.
5677 Airline Road
Arlington, TN 38002

Name: Pascal Girin Sign:

Title: EVP & Chief Operating Officer

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

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Appendix

510(K) NUMBER	APPROVAL DATE	PRODUCT	510(k) Applicant
K873857/A1	12/1/1987	WHITESIDE ORTHOLOC REVISION HIP STEM PROSTHESIS	DOW CORNING WRIGHT
K864626/A1	12/15/1986	CANCELLOUS BONE SCREW	DOW CORNING WRIGHT
K864627/A1	2/4/1987	WHITESIDE ORTHOLOC II METAL BACKED PATELLA	DOW CORNING WRIGHT
K870174/A1	2/6/1987	MCCUTCHEN FEMORAL HIP PROSTHESIS	DOW CORNING WRIGHT
K902538/A1	7/6/1990	WHITESIDE ORTHOLOC MODULAR TIBIAL AUGMENTATION	DOW CORNING WRIGHT
K905076/A1	2/13/1991	WHITESIDE ORTHOLOC MODULAR TIBIAL CONSTRAIN.INSERT	DOW CORNING WRIGHT
K910596/A1	5/29/1991	DCW MODULAR DISTAL FEMORAL SYSTEM	DOW CORNING WRIGHT
K911595/A1	7/12/1991	INFINITY(TM) POROUS-COATED TROCHANTERIC MODULE	DOW CORNING WRIGHT
K922159/A1	10/15/1993	INFINITY POROUS-COATED TROCHANTERIC MODULE	WRIGHT MEDICAL TECHNOLOGY INC.
K933871/A3	2/23/1994	BRIDGE(TM) HIP SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K933570/A2	3/7/1994	RESOLUTION(TM) HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K933281/A5	6/7/1994	S.O.S. PROXIMAL FEMUR	WRIGHT MEDICAL TECHNOLOGY INC.
K933289/A7	8/25/1994	THICK TIBIAL INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K933290/A4	9/1/1994	ORTHOLOC ADVANTIM	WRIGHT MEDICAL TECHNOLOGY INC.
K934620 A6	9/1/1994	ORTHOLOC ADVANTIM FIXED STEM NON-POROUS TIBIAL BASE	WRIGHT MEDICAL TECHNOLOGY INC.
K942115 A2	9/28/1994	INFINITY REVISION HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K940235 A8	10/5/1994	ORTHOLOC ADVANTIM PS LSI TIBIAL INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K944845 A2	12/15/1994	ORTHOLOC ADVANTIM MODULAR FEMORAL AUGMENT COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K941755 A1	1/17/1995	ORTHOLOC ADVANTIM LSI POSTERIOR STABLIZED ALL POLYTHYLENE TIBIAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.

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K971429 A1	7/9/1997	INTERSEAL ACETABULAR SCREW HOLE PLUG	WRIGHT MEDICAL TECHNOLOGY INC.
K972626 A1	9/29/1997	ADVANCE KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K971056 A1	10/3/1997	MAGELLAN MAGNETIC DISTAL TARGETING SYSTEM(PROPOSED NAME) PRODUCT LINE EXTENSION	WRIGHT MEDICAL TECHNOLOGY INC.
K972641 A3	10/9/1997	DUAL OFFSET PERFECTA IMC HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K972770 A3	10/21/1997	ADVANCE ULTRA-CONGRUENT TIBIAL INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K973296 A4	11/24/1997	EXTEND HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K973524 A4	12/12/1997	ADVANCE MODULAR TIBIAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K974328 A1	1/30/1998	ADVANCE TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K982390 A1	9/14/1998	CONCISE COMPRESSION HIP SCREW SYSTEM (STERILE)	WRIGHT MEDICAL TECHNOLOGY INC.
K990030 A2	2/3/1999	ADVANCED REVISION PRODUCT LINE EXTENSION	WRIGHT MEDICAL TECHNOLOGY INC.
K991123 A2	6/1/1999	PERFECTA RS LATERALIZED HIP STEM BRIDGE HIP SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K993371 A2	12/20/1999	SADDLE SHAPED PATELLA	WRIGHT MEDICAL TECHNOLOGY INC.
K002149 A1	8/31/2000	LINEAGE ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K003016 A1	12/13/2000	PRO-FEMUR R	WRIGHT MEDICAL TECHNOLOGY INC.
K004032 A2	2/15/2001	PERFECTA AND EXTEND	WRIGHT MEDICAL TECHNOLOGY INC.
K004043 A2	7/13/2001	METAL TRANSCEND ARTICULATION SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K012091 A2	10/3/2001	PRO-FEMUR	WRIGHT MEDICAL TECHNOLOGY INC.
K012591 A1	11/2/2001	ADVANCE UNICONDYLAR KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K013035 A1	12/7/2001	GUARDIAN LIMB SALVAGE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K014171 A2	3/15/2002	ADVANCE UNICONDYLAR KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K021349 A1	7/1/2002	METAL TRANSCEND ARTICULATION SYSTEM	WRIGHT MEDICAL

K945087 A1	3/17/1995	ORTHOLOC ADVANTIM POROUS COATED TIBIAL BASE	WRIGHT MEDICAL TECHNOLOGY INC.
K944856 A2	5/16/1995	ORTHOMET ACETABULAR ROOF REINFORCEMENT RING	WRIGHT MEDICAL TECHNOLOGY INC.
K950418 A1	6/15/1995	ALPHA POROUS COATED FEMORAL COMPONENT (SUBJECT TO WMTI MARKETING APPROVAL)	WRIGHT MEDICAL TECHNOLOGY INC.
K952640 A2	7/31/1995	CANNULATED PLUS HIP SCREW	WRIGHT MEDICAL TECHNOLOGY INC.
K953025 A1	9/8/1995	SLT 28MM XXL FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
K944689 A2	10/20/1995	ZIRCONIA CERAMIC FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
K954262 A2	11/3/1995	NEXUS II FEMORAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K951139 A1	11/22/1995	ALPHA LONG STEM FEMORAL COMPONENT (SUBJECT TO WMTI MARKETING APPROVAL)	WRIGHT MEDICAL TECHNOLOGY INC.
K954288 A6	11/30/1995	EXTEND HIP SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K945774 A2	12/28/1995	BETA FEMORAL HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K955229 A3	1/18/1996	WRIGHT MEDICAL TECHNOLOGY SAWBLADES	WRIGHT MEDICAL TECHNOLOGY INC.
K953439 A1	1/30/1996	ULTRACK TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K955837 A1	3/4/1996	CANNULATED PLUS HIP SCREW (STERILE)	WRIGHT MEDICAL TECHNOLOGY INC.
K960617 A3	5/8/1996	ADVANCE TIBIAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K961900 A1	7/25/1996	TIBIAL TRAY PLUG A PRODUCT LINE ADDITION TO THE AXIOM TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K962267 A3	9/10/1996	PERFECTA PS REVISION STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K955553 A1	10/24/1996	PERFECTA REVISION HIP SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K964218 A2	1/8/1997	PERFECTA PLASMA SPRAY HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K964249 A1	1/14/1997	BRIDGE LONG STEM FEMORAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
K971135 A2	6/5/1997	MAGELLAN INTRAMEDULLARY FEMORAL NAIL SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.

			(LARGER SIZES)	TECHNOLOGY INC.
	K021346 A1	7/2/2002	STEM HIP REPLACEMENT SYSTEM MODEL PHA002XX	WRIGHT MEDICAL TECHNOLOGY INC.
	K021489 A1	12/4/2002	REPIPHYSIS LIMB SALVAGE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K030193 A2	2/20/2003	ADVANCE LESS CONFORMING TIBIAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K031963 A1	10/31/2003	CONSERVE PLUS SPIKED ACETABULAR SHELLS AND CONSERVE TOTAL 56MM FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K033890 A1	1/15/2004	ADVANCE DOUBLE HIGH INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K034028 A1	3/11/2004	ATH FEMORAL STEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K041114 A2	5/28/2004	PROFEMUR TAPERED HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K041425 A2	6/25/2004	CONSERVE PLUS REVISION SHELL AND CONSERVE PLUS THICK SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
NE/DNAMD	K041586 A1	7/9/2004	PROFEMUR S HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K031402 A3	11/22/2004	PERFECTA FEMORAL STEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K042530 A1	12/17/2004	CONSERVE PLUS HA ACETABULAR SHELLS	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K043083 A1	4/18/2005	ADVANCE HA COATED SPIKED TIBIAL BASE AND ADVANCE HA COATED MODULAR KEEL	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K043073 A1	5/4/2005	PROCOTYL-E ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K051348 A3	8/19/2005	CONSERVE TOTAL FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K051995 A1	8/22/2005	PROFEMUR RENAISSANCE HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K043099 A1	9/29/2005	LINEAGE HA ACETABULAR SHELLS	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K052026 A2	12/5/2005	LINEAGE A-CLASS POLY LINER	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K053588 A1	1/13/2006	PROFEMUR LX HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K052915 A2	1/27/2006	PROFEMUR XTR HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K060356 A1	4/18/2006	CONSERVE PLUS QUADRAFIX ACETABULAR SHELL	WRIGHT MEDICAL TECHNOLOGY INC.

	K060358 A1	5/10/2006	PROFEMUR TL HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
	K061547 A1	7/3/2006	DYNASTY ACETABULAR SHELL; DYNASTY A-CLASS POLY ACETABULAR LINER	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K061223/A1	8/18/2006	ADVANCE TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K062693/A1	9/29/2006	GLADIATOR BIPOLAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K062960/A3	12/1/2006	CONSERVE FEMORAL RESURFACING COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K061844/A1	12/6/2006	DYNASTY ACETABULAR SHELL AND COCR ACETABULAR LINER	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K063731/A1	3/2/2007	ADVANCE STATURE FEMORAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K063128/A1	3/21/2007	ADVANCE SPIKED POROUS TIBIAL BASE	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K070785/A1	7/11/2007	DYNASTY ACETABULAR SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K072367/A1	1/9/2008	REPIPHYSIS LIMB SALVAGE PROXIMAL FEMUR AND TOTAL FEMUR	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K072656/A1	2/6/2008	DYNASTY CERAMIC FEMORAL HEAD	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K080663/A1	4/8/2008	PROFEMUR LX REVISION 5/8 COATED HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K081090/A1	5/15/2008	PROFEMUR LX 5/8 COATED HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K082673/A1	12/12/2008	CONSERVE PRESSFIT FEMORAL COMPONENT	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K081479/A1	2/20/2009	ADVANCE A-CLASS TIBIAL INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K082924/A1	3/6/2009	DYNASTY POROUS ACETABULAR SHELL DYNASTY POLYETHYLENE ACETABULAR LINER DYNASTY METAL ACETABULAR LINER	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K092201/A1	8/20/2009	ADVANCE 913 MEDIAL PIVOT TIBIAL INSERT ADVANCE 913 MEDIAL PIVOT TIBIAL BASE	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K091423/A1	8/25/2009	PROFEMUR HIP SYSTEM MODULAR NECKS	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K093552/A1	3/4/2010	EVOLUTION MP TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
OR/DOD	K100866/A1	4/28/2010	PROFEMUR HIP SYSTEM MODULAR NECKS	WRIGHT MEDICAL TECHNOLOGY INC.

K093405	5/25/2010	PROPHECY PRE-OPERATIVE NAVIGATION ALIGNMENT GUIDES	WRIGHT MEDICAL TECHNOLOGY INC.
K100973	8/10/2010	EVOLUTION UNICONDYLAR KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K102565	12/22/2010	ANTERIOR APPROACH HIP SURGERY INSTRUMENTS	WRIGHT MEDICAL TECHNOLOGY INC.
K102380	1/7/2011	EVOLUTION MP TOTAL KNEE SYSTEM	WRIGHT MEDICAL TECHNOLOGY INC.
K110029	4/19/2011	CONSERVE BIO FOAM SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K110399	5/10/2011	GLADIATOR PLASMA CLASSIC HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K111698	8/19/2011	PROFEMUR(R) E CEMENTLESS HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K111699	8/19/2011	PROFEMUR(R) Z TITANIUM PLASMA SPRAYED HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K111910	10/14/2011	GLADIATOR HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K103598	10/17/2011	PROPHECY PRE-OPERATIVE NAVIGATION ALIGNMENT GUIDES	WRIGHT MEDICAL TECHNOLOGY INC.
K113019	11/10/2011	PROFEMUR XM WINGLESS DISTAL CENTRALIZER PERFECTA DISTAL CENTRALIZER	WRIGHT MEDICAL TECHNOLOGY INC.
K112150	11/23/2011	PROFEMUR GLADIATOR HA HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K113325	12/9/2011	EVOLUTION MP ADAPTIVE CS INSERT	WRIGHT MEDICAL TECHNOLOGY INC.
K112080	12/28/2011	PRESERVE HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K113322	2/3/2012	CONSERVE THIN SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K121544	7/30/2012	DYNASTY BIOFOAM SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K121221	8/9/2012	PROFEMUR Z REVISION HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K122778	10/11/2012	PROFEMUR Z REVISION HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.
K122382	10/22/2012	DYNASTY BIOFOAM SHELL	WRIGHT MEDICAL TECHNOLOGY INC.
K123434	2/5/2013	PROFEMUR Z CLASSIC STEMS	WRIGHT MEDICAL TECHNOLOGY INC.
K123688	2/8/2013	PROFEMUR TL CLASSIC HIP STEM	WRIGHT MEDICAL TECHNOLOGY INC.

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WRIGHT.

December 17, 2013

K 140043

FDA CDRH DMC

JAN 08 2014

Received

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Premarket Notification
DYNASTY® Acetabular System with Ceramic

Dear Sir or Madam:

Enclosed are two copies (one hard copy and one exact electronic copy) of a Traditional 510(k) for the DYNASTY® Acetabular System with Ceramic which will be marketed by Wright Medical Technology, Inc. The eCopy is an exact duplicate of the paper copy. The subject devices are acetabular shells, polyethylene liners, and alumina composite femoral heads that are substantially equivalent to the LINEAGE® Acetabular System (K002149 shells; K052026 liners) and DYNASTY® Acetabular System (K130376 heads), respectively.

The subject devices will remain intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients. The modifications described in this 510(k) do not alter the fundamental scientific technology of the device. In addition, all modifications were made in accordance with the company's design control process. Accordingly, Wright considers the Traditional 510(k) to be the appropriate process. Subject regulatory information is as follows:

Proprietary Name:	DYNASTY® Shell, DYNASTY® A-CLASS® Crosslinked Poly Liner, BIOLOX® DELTA Femoral Head
Common Name:	Acetabular Shell, Liner, and Femoral Head
Recommended Classification:	888.3353 Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented – Class II
Subject Panel Code and Product Code:	Orthopedics/87/ LZO

Headquarters
Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002 **901.867.9971** phone
www.wmt.com

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Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	x	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		x
Does the device contain components derived from a tissue or other biologic source?		x
Is the device provided sterile?	x	
Is the device intended for single use?	x	
Is the device a reprocessed single use device?		x
If yes, does this device type require reprocessed validation data?		x
Does the device contain a drug?		x
Does the device contain a biologic?		x
Does the device use software?		x
Does the submission include clinical information?		x
Is the device implanted?	x	

This Premarket Notification is submitted in accordance with 21 CFR 807, Subpart E. FDA Guidance Documents "*Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s*" issued on August 12, 2005, "*Refuse to Accept Policy for 510(k)s*" issued on August 13, 2012, "*Guidance Document For The Preparation of Premarket Notification For Ceramic Ball Hip Systems*" issued on January 10, 1995, "*Guidance Document for Testing Non-Articulating, 'Mechanically Locked', Modular Implant Components*" issued on May 1, 1995, and "*eCopy Program for medical Device Submissions*" dated October 10, 2013 were used for formatting of this submission. All sections are referenced by a Table of Contents immediately following this letter. The Refuse to Accept checklist for Special 510(k)s is being submitted in place of the 510(k) Screening Checklist, as it is specific to the content of Traditional 510(k)s.

This Premarket Notification includes trade secret and commercial information that is privileged or confidential and, in accordance with 21 CFR 20.61, is not available for public disclosure. In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary is included in this notification.

In accordance with MDUFMA, Wright Medical Technology, Inc. has sent the required User Fee. A copy of the Medical Device User Fee Cover Sheet is provided as the first section of this submission. (b)(4)Trade Secret Process

(b)(4)Trade Secret Process

All correspondence concerning this submission should be directed to:

Matt Paul
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

If you have any questions regarding this notification or require additional information, please contact me by telephone at (901) 867-4350, by facsimile at (901) 867-4190, or by email at matt.paul@wmt.com.

Sincerely,

Matt Paul, MSc
Project Manager, Regulatory Affairs

Dynasty Acetabular System with Ceramic - Matt Paul

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016, See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Secret
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

WRIGHT MEDICAL TECHNOLOGIES INC
5677 AIRLINE ROAD
ARLINGTON
TN 38002
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)

2. CONTACT NAME
Gloria Grandberry
2.1 E-MAIL ADDRESS
gloria.grandberry@wmt.com
2.2 TELEPHONE NUMBER (include Area code)
901-867-4582
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
901-867-4190

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)
(4)Trade Secret
02-Dec-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Wright Medical Technology, Inc. P.O. Box 156, Arlington, Tennessee 38002, Phone (901) 867-9971

Check No.: (b)(4)Trade

Date: 12/05/13 Vendor Name: U.S. FOOD AND DRUG ADMINISTRATION Vendor No.: 100421

Invoice Number	Invoice Date	Description	Gross Amount	Discount	Net Amount
(b)(4)Trade Secret Process					

This is your statement of payment for items shown above.
Please detach and retain for your records.
05/12/2013-10:58:15
USFIN0001-3490962

Totals: (b)(4)Trade Secret Process

(b)(4)Trade Secret Process

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
December 17, 2013	(b)(4)Trade Secret Process	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Wright Medical Technology, Inc.	Establishment Registration Number *(if known)*: 1043534		
Division Name *(if applicable)*: Regulatory Affairs	Phone Number *(including area code)*: (901) 867-4350		
Street Address: 5677 Airline Road	FAX Number *(including area code)*: (901) 867-4190		
City: Arlington	State / Province: TN	ZIP/Postal Code: 38002	Country: USA
Contact Name: Matt Paul			
Contact Title: Regulatory Affairs Project Manager	Contact E-mail Address: Matt.Paul@wmt.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify)*:

Line Addition

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LZO	2	LPH	3	JDI	4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K002149 (Shell)	1	LINEAGE® Acetabular System	1	Wright Medical Technology, Inc.
2	K052026 (Liner)	2	LINEAGE A-CLASS Poly Liner	2	Wright Medical Technology, Inc.
3	K130376 (Head)	3	DYNASTY® Acetabular System with Ceramic	3	Wright Medical Technology, Inc.
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Femoral Head, Acetabular Liner, Acetabular Shell

	Trade or Proprietary or Model Name for This Device		Model Number
1	DYNASTY® Shell	1	DSPCGB46, DSPCGB48
2	DYNASTY® A-CLASS® Crosslinked Poly Liner	2	DLXPGB28, DLXPLB28
3	BIOLOX® DELTA Femoral Head	3	PHA04402, PHA04404, PHA04408
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K133426	2 K130376	3 K070785	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LZO	21 CFR Part 888.3353	[ ] Class I [x] Class II
Classification Panel: Orthopedics		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

Wright Medical total hip systems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- inflammatory degenerative joint disease such as rheumatoid arthritis;
- correction of functional deformity; and,
- revision procedures where other treatments or devices have failed

Note: **Submission of the information entered in Section H does not affect the need to submit device establishment registration.**	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number 1043534	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name Wright Medical Technology, Inc.		Establishment Registration Number 1043534
Division Name *(if applicable)*		Phone Number *(including area code)* (901) 867-4350
Street Address 5677 Airline Road		FAX Number *(including area code)* (901) 867-4190

City	State / Province	ZIP Code	Country
Arlington	TN	38002	USA

Contact Name	Contact Title	Contact E-mail Address
Matt Paul	Regulatory Affairs Project Manager	Matt.Paul@wmt.com

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	11137-1	ANSI/AAMI/ISO	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2006	
2	11135	ANSI/AAMI/ISO	Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization	2008	
3	6474-2	ISO	Implants for surgery -- Ceramic materials -- Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement	2012	
4	F136	ASTM	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401	12a	
5	F648	ASTM	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	13	
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Wright Medical Technology, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Dec 17, 2013

3. ADDRESS *(Number, Street, State, and ZIP Code)*
5677 Airline Road
Arlington, Tennessee
38002

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) (901) 867-4350
(Fax) (901) 867-4190

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

DYNASTY® Acetabular System with Ceramic

Classification: Class II

Model Name and Model Number - See Attached Exhibit 01

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Matt Paul
(Title) Regulatory Affairs Project Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
5677 Airline Road
Arlington, Tennessee
38002

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) +1 (901) 867-4350
(Fax) +1 (901) 867-4190

15. DATE OF CERTIFICATION
Dec 17, 2013

PSC Publishing Services (301) 443-6740 EF

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter -** This is the name of the sponsor/applicant/submitter of the drug/biologic/device applicatic submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date -** This is the date of the application/submission which the certification accompanies.
3. **& 4. -** Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission -** Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number -** If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number -** In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification -** This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers -** If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative -** The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11 -** Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. **& 14. -** Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

December 17, 2013

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Premarket Notification
DYNASTY® Acetabular System with Ceramic

Dear Sir or Madam:

Enclosed are two copies (one hard copy and one exact electronic copy) of a Traditional 510(k) for the DYNASTY® Acetabular System with Ceramic which will be marketed by Wright Medical Technology, Inc. The eCopy is an exact duplicate of the paper copy. The subject devices are acetabular shells, polyethylene liners, and alumina composite femoral heads that are substantially equivalent to the LINEAGE® Acetabular System (K002149 shells; K052026 liners) and DYNASTY® Acetabular System (K130376 heads), respectively.

The subject devices will remain intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients. The modifications described in this 510(k) do not alter the fundamental scientific technology of the device. In addition, all modifications were made in accordance with the company's design control process. Accordingly, Wright considers the Traditional 510(k) to be the appropriate process. Subject regulatory information is as follows:

Proprietary Name:	DYNASTY® Shell, DYNASTY® A-CLASS® Crosslinked Poly Liner, BIOLOX® DELTA Femoral Head
Common Name:	Acetabular Shell, Liner, and Femoral Head
Recommended Classification:	888.3353 Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented – Class II
Subject Panel Code and Product Code:	Orthopedics/87/ LZO

Headquarters
Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002 **901.867.9971** phone
www.wmt.com

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	x	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		x
Does the device contain components derived from a tissue or other biologic source?		x
Is the device provided sterile?	x	
Is the device intended for single use?	x	
Is the device a reprocessed single use device?		x
If yes, does this device type require reprocessed validation data?		x
Does the device contain a drug?		x
Does the device contain a biologic?		x
Does the device use software?		x
Does the submission include clinical information?		x
Is the device implanted?	x	

This Premarket Notification is submitted in accordance with 21 CFR 807, Subpart E. FDA Guidance Documents "*Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s*" issued on August 12, 2005, "*Refuse to Accept Policy for 510(k)s*" issued on August 13, 2012, "*Guidance Document For The Preparation of Premarket Notification For Ceramic Ball Hip Systems*" issued on January 10, 1995, "*Guidance Document for Testing Non-Articulating, 'Mechanically Locked', Modular Implant Components*" issued on May 1, 1995, and "*eCopy Program for medical Device Submissions"* dated October 10, 2013 were used for formatting of this submission. All sections are referenced by a Table of Contents immediately following this letter. The Refuse to Accept checklist for Special 510(k)s is being submitted in place of the 510(k) Screening Checklist, as it is specific to the content of Traditional 510(k)s.

This Premarket Notification includes trade secret and commercial information that is privileged or confidential and, in accordance with 21 CFR 20.61, is not available for public disclosure. In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary is included in this notification.

In accordance with MDUFMA, Wright Medical Technology, Inc. has sent the required User Fee. A copy of the Medical Device User Fee Cover Sheet is provided as the first section of this submission. (b)(4)Trade Secret Process [redacted]

All correspondence concerning this submission should be directed to:

Matt Paul
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

If you have any questions regarding this notification or require additional information, please contact me by telephone at (901) 867-4350, by facsimile at (901) 867-4190, or by email at matt.paul@wmt.com.

Sincerely,

Matt Paul, MSc
Project Manager, Regulatory Affairs

TABLE OF CONTENTS

Contains Nonbinding Recommendations

Acceptance Checklist
for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: _____ **Date Received by DCC:** _____

Lead Reviewer Name: _____ **Branch:** _____ **Division:** _____ **Office:** _____

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	✓	☐
Comments:		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	✓	☐
Comments: Orthopaedics		
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:		

a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, skip this question.	☐	☐
Comments: No RFD Submitted		
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	☑	☐
Comments: Class II Device type		
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.	☐	☑
Comments: No pending PMA		
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.	☐	☑

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

If the answer to 6 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation*		
	Yes	**No**
a. Submission contains Table of Contents	☑	☐
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☑	☐
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).*	☑	☐
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	☑	☐
Comments: Tab 005 is Table of Contents. Traditional 510(k) identified in Tab 004 Cover Letter.		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		☑		☐
		Comments:				
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):		☑		☐
		a.	Device trade name or proprietary name Tab 002CDRH Sheet;004Letter	☑		☐
		b.	Device common name Tabs 002 CDRH Sheet; 004 Letter	☑		☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☑		☐
		Comments: Tabs 002 CDRH Sheet; 004 Cover Letter				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		☑		☐
		Comments: Tab 007 Indications for Use Statement				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) in Comments.*		☑		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	☑	☐	☐
		b.	Statement contains all elements per 21 CFR 807.93	☐	☑	☐
		Comments: Tab 008 is 510(k) Summary of Safety and Effectiveness				
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. Select "Yes" if statement is present and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).*		☑		☐
		Comments: Tab 010 Truthful and Accuracy Statement				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	6.	Submission contains Class III Summary and Certification *See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).*		☐	☑	☐
		Comments: Subject device is Class II. Tab 011 states Class III Summary is not applicable.				
	7.	Submission contains clinical data *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐	☑	
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry-Financial Disclosures by Clinical Investigators*	☐	☐	☐
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☐	☐	☐
		Comments: No Clinical Data Included. As declared on Form 3674 in Tab 003.				
	8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654) *There should be a completed form for each referenced national or international standard.* *Select "N/A" only if submission does not reference any standards.*		☑	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		Comments: Tab 009 contains FDA Form 3654				
	9.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. *This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions*(b)(4)Trade Secret Process [redacted]			☑		☐
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. *To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review.* For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm). Once finalized, this guidance will represent the	☐	☑	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			Agency's current thinking on this topic. *Select "N/A" if the submitter states there were no prior submissions in criterion above.*			
		Comments: Bottom of page 4 in Tab 012, section 'Submission History' refers to Table 8 corrected data.				
B.	**Device Description**					
	10.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☑	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☑	☐	☐
		Comments: Tab 012 PremarketNotification 'Materials' section cites Ceramic guidance.Data follows throughout.				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	☑		☐
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☑		☐
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.*	☑	☐	☐
		Comments: Surgical technique in Tab 034 Exhibit 07. Parts list provided in 023 Exhibit 01.				
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. *In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.* *Select "N/A" if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).*		☑	☐	☐
		Comments: Tab 024 Exhibit 02 subject device drawings. 025 Exhibit 03 predicate device drawings.				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*			☐	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device. Tab 012 page 6; Tab 017.	☑		☐
		b.	Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.* Tab 012, implants begin on page 6. Tab 017 lists instruments.	☑	☐	☐
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.*	☑	☐	☐
		Comments: Tab 012, implants page 6. Tab 017, instruments. Also Tab 034: Exhibit 07, beginning on page 7.				
C.	**Substantial Equivalence Discussion**					
	14.	Submitter has identified a predicate(s) device		☑		☐
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidan*	☑		☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			ce/ComplianceActivities/ucm072746.htm).			
		b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☑		☐
		Comments: Tab 012 page 1 predicates identified. Tab 026: Exhibit 4, clearance letters. Tabs 008; 013; 020.				
	15.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use	☑		☐
		b.	Technology, including features, materials, and principles of operation	☑		☐
		Comments: Tab 012 indications on page 11. Technology comparison begins on page 12.				
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in*			☑	☐	☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed.				
		Comments: Tab 012 beginning on page 11. Tab 013 Substantial Equivalence. Tab 020 Bench testing.				
D.	**Proposed Labeling (see also 21 CFR part 801)** *If in vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted. These criteria will be omitted from the checklist if "N/A" is selected. IVD labeling is addressed in section 21 below.*				☐	
	17.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use		☑		☐
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	☑		☐
		b.	Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☑		☐
		Comments: Tabs 032 to 035: Exhibit 7 Proposed Labels, Symbols Legend, Surgical Technique, Package Insert.				
	18.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*		☑	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		Comments: Tab 032: Exhibit 7 Sample Label				
	19.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	☑		☐
		b.	Labeling includes device common or usual name (21 CFR 801.61) *Select "N/A" if device is for prescription use only.*	☑	☐	☐
		Comments: Tab 032: Exhibit 7 Sample Label				
	20.	a.	If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.* Tabs 032-035: Exhibit7 Proposed Labeling	☑	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.* Tabs 032-035: Exhibit7 Proposed Labeling	☑	☐	☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		c.	If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	☑	☐
		Comments: No special controls				
	21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*		☐	☑	☐
E.	**Sterilization** *If in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	
	Submission states that the device and/or accessories are: (*one of the below must be checked*) ☑ provided sterile ☐ provided non-sterile but sterilized by the end user ☐ non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from*					☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	the checklist. *If information regarding the sterility status of the device is not provided, select "No."*					
	Comments: Tab 016 Sterilization and Shelf Life					
	22.	Assessment of the need for sterilization information				
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	☑	☐	☐
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized	☑	☐	☐
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	☑	☐	☐
		Comments: Tab 016 Sterilization and Shelf Life. Tab 035: Exhibit 07 Package Insert, instructions on pages 7-9.				
	23.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.*			☐	
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	☑		☐
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	☑		☐
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum	☑	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*			
		d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☑		☐
		e.	Sterility Assurance Level (SAL) stated	☑		☐
		Comments: Tab 016 summary details. Process details in Tabs 029 and 030 (Exhibits 06)				
	24.	If the device, and/or accessory, and/or a component is end user sterilized: *Select "N/A" if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.*			☐	
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.) Tab 016 Sterilization and Shelf Life.	☐		☐
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. Overkill method AAMI TIR 12 noted in Tab 016. *Note, the sterilization validation is not required.*	☐		☐
		c.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.) Tab 016 Sterilization and Shelf Life.	☐		☐
		d.	Submission includes sterilization instructions for end user	☐		☐
		Comments: Tab 035: Exhibit 07 Package Insert, instructions on pages 7-9.				
	25.	a.	If there are requirements regarding sterility, such as special	☑	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.* Ceramics guidance. Tabs 016 and 029.			
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.* Ceramics guidance. Tabs 016 and 029.	☑	☐	☐
		c.	If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a*	☐	☑	

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			special controls document have been addressed should be assessed during the substantive review.			
		Comments:				
F.	**Shelf Life**					
	26.	Proposed shelf life/ expiration date stated *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*		☑	☐	☐
		Comments: Tab 031 Exhibit 06				
	27.	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. *Select "N/A" if the device is not provided sterile.*		☑	☐	☐
		Comments: Tab 016 Sterilization and Shelf Life, Tab 031: Exhibit 06 Shelf Life Statement				
	28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.		☑		☐
		Comments: Tab 016 Sterilization and Shelf Life. 036 Material reference MAF197. 020 Bench Testing.				
G.	**Biocompatibility** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	
	Submission states that there: (*one of the below must be checked*) ☑ are					☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
	☐ are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."*				
	Comments: Tab 017 Biocompatibility				
	29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	☑		☐
		Comments: Tab 013, Materials on page 5. Tab 017 Biocompatibility. Tab 036: Exhibit 9 CeramTec AG Master File Authorization Letter.			
	30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	☑		☐
		Comments: Tab 017 Biocompatibility			
	31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☑		☐
		Comments: Tab 017 Biocompatibility			
H.	**Software**				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
	Submission states that the device: (*one of the below must be checked*) ☐ does ☑ does not contain software/firmware. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."*			☐
	Comments: Tab 018 Software			
	32. Submission includes a statement of software level of concern and rationale for the software level of concern	☐		☐
	Comments:			
	33. All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☐		☐
	Comments:			
I.	**EMC and Electrical Safety**			
	Submission states that the device: (*one of the below must be checked*) ☐ does ☑ does not require EMC and Electrical Safety evaluation.			☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes) An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."*			
	Comments: 020-Electromagnetic Compatibility and Electrical Safety tab p. 61			
	34. Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐		☐
	Comments:			
	35. Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐		☐
	Comments:			

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
J.	**Performance Data – General** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.*				☐	
	Comments:					
	36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*		☑	☐	☐
		Comments: Tabs 027 & 028 (Exhibits 05) contain full test reports				
	37.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.* Tab 020. Tabs 028 & 029 (Exhibits 05)	☑	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative	☑	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.* Tab 020. Tabs 028 & 029 (Exhibits 05)			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	☑	☐
		Comments:				
	38.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*			☐	
		a.	Legible reprints or a summary of each article	☑		☐
		b.	Discussion of how each article is applicable to support the	☑		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			substantial equivalence of the subject device to the predicate.			
		Comments: 029-Exhibit 5: ER13-0001 p. 186 & 288, Footnotes [5] & [9] on p. 188 and 187 respectively				
	39.	For each completed nonclinical (i.e., animal) study conducted, *Select "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist,*			☑	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐		☐
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐		☐
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐		☐
		Comments:				
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**					
	Submission indicates that device: (*one of the below must be checked*) ☐ is ☑ is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	Comments:					

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				
		a.	Precision/reproducibility	☐	☐	☐
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	☐	☐	☐
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐
		d.	Analytical specificity	☐	☐	☐
		Comments:				
	41.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the	☐	☐	☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	☐	☐
		Comments:				

Decision: Accept ___ Refuse to Accept ___

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Reviewer Signature: _____ Date: _____

Supervisory Signature: _____ Date: _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Dynasty Acetabular System

Indications for Use *(Describe)*
The DYNASTY® Acetabular System is intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.
1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed
Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty. Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the DYNASTY® Acetabular System with Ceramic.

Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd, Arlington TN, 38002 (800) 238-7188
Date:	December 17, 2013
Contact Person:	Matt Paul *Project Manager, Regulatory Affairs*
Proprietary Name:	DYNASTY® Acetabular System with Ceramic
Common Name:	Acetabular Shell, Acetabular Liner, Femoral Head
Classification Name and Reference:	888.3353 prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented Class II
Subject Product Code and Panel Code:	Orthopedics/87/LZO
Predicate Devices:	DYNASTY® Acetabular System with Ceramic 510(k): K130376 Shell: K002149; Liner: K052026; Head: K130376

DEVICE INFORMATION

A. Intended Use

Wright Medical total hip systems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.

B. Device Description

The DYNASTY® Acetabular System with Ceramic contains femoral heads in size 28mm manufactured from alumina matrix composite, mating acetabular liners manufactured from crosslinked polyethylene, and beaded acetabular shells manufactured from titanium alloy.

C. Substantial Equivalence Information

The subject DYNASTY® Acetabular System with Ceramic is indicated to be paired with the following existing acetabular components summarized in Table 1. These shell types were cleared in K130376 for use with larger diameter BIOLOX® DELTA ceramic-polyethylene bearings.

Table 1. Compatible Shells, Including 510(k) Information. All shells were cleared for use with Biolox Delta heads and polyethylene liners in K130376.

510(k)	Device Name
K122382	DYNASTY® 10 Hole Revision Shells
K122382	DYNASTY® BIOFOAM® 3-Hole Shells
K122382	DYNASTY® BIOFOAM® Solid Shells
K122382	DYNASTY® BIOFOAM® 5 Hole Shells
K082924	DYNASTY® BIOFOAM® Shells
K061547; cleared for alumina-polyethylene under K072656	DYNASTY® Porous 3-Hole Shells, 50 to 58mm
K070785; cleared for alumina -polyethylene under K072656	DYNASTY® Porous 3-Hole Shells, 60 to 68mm

The subject DYNASTY® Acetabular System with Ceramic is indicated to be paired with the following femoral components summarized in Table 2.

Table 2. Compatible Femoral Components, Including 510(k) Information. All femoral stems were cleared for use with Biolox Delta heads in K130376, except K130984.

510(k)	Device Name
K003016	PRO-FEMUR R
K012091	PRO-FEMUR
K021346	STEM HIP REPLACEMENT SYSTEM
K041114	PROFEMUR TAPERED HIP STEM
K041586	PROFEMUR S HIP STEM
K051995	PROFEMUR RENAISSANCE HIP STEM
K052915	PROFEMUR XTR HIP STEM
K053588	PROFEMUR LX HIP STEM
K060358	PROFEMUR TL HIP STEM
K080663	PROFEMUR LX REVISION 5/8 COATED HIP STEM
K081090	PROFEMUR LX 5/8 COATED HIP STEM
K091423 K100866	PROFEMUR HIP SYSTEM MODULAR NECKS
K110399	GLADIATOR PLASMA CLASSIC HIP STEM
K111698	PROFEMUR(R) E CEMENTLESS HIP STEM
K111699	PROFEMUR(R) Z TITANIUM PLASMA SPRAYED HIP STEM
K111910	GLADIATOR HIP STEM
K112080	PRESERVE HIP STEM
K112150	PROFEMUR GLADIATOR HA HIP STEM
K121221	PROFEMUR Z REVISION HIP STEM
K123434	PROFEMUR Z CLASSIC STEM
K123688	PROFEMUR TL CLASSIC STEM
K130984	PROFEMUR RENAISSANCE CLASSIC STEM

The design features of the subject femoral head devices are substantially equivalent to those of the predicate DYNASTY® Acetabular system devices cleared under K130376. The design features of the subject acetabular liner and shell devices are substantially equivalent to those of the predicate LINEAGE® Acetabular system devices cleared under K052026 and K002149. The indications of the subject device are identical to the predicate. Specific warnings are added in the package insert. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. Validation of sterilization residuals by ethylene oxide was conducted on devices cleared in K893685 and K002149; this validation was submitted in K130376, is applicable to the subject devices and is included again in this notification. The safety and effectiveness of the DYNASTY® Acetabular System with Ceramic is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

D. Nonclinical Testing

The subject DYNASTY® Acetabular System with Ceramic was evaluated mechanically, tribologically, and chemically. Wear of the subject bearing was evaluated for comparison to a metal-poly bearing that was cleared under K052026. The mechanical testing on the subject and predicate devices was performed on wrought Cobalt Chrome modular neck spigots cleared under K091423 and K100866. The testing shows that it can be concluded that the subject ceramic material can be expected to perform well under normal physiological chemical and mechanical conditions.

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Conclusion

The design features of the subject devices are substantially equivalent to the predicate devices. The instrument list and materials remain identical to those cleared under K122382 and K130376. The safety and effectiveness of the DYNASTY® Acetabular System with Ceramic is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 11137-1:2006 Sterilization of health care products - Radiation - Part 1: Requirements for development, validatio

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 14-297	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☑
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 11137-1:2006 Sterilization of health care products - Radiation - Part 1: Requirements for development, validatio

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for de	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

N/A

DESCRIPTION

JUSTIFICATION

Fully Conformed

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11135 Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-228	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 11135 Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11135	Validation and Routine Control of Ethylene Oxide Sterilization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦
N/A

DESCRIPTION

JUSTIFICATION
Fully Conformed

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 6474-2 Implants for surgery - Ceramic materials - Part 2: Composite materials based on high purity alumina matrix with zirco

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: Guidance Document For The Preparation of Premarket Notification For Ceramic Ball Hip Systems

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 6474-2 Implants for surgery - Ceramic materials - Part 2: Composite materials based on high purity alumina matrix with zirco

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6474-2	Implants for surgery - Ceramic materials - Part 2: Composite materials based	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

N/A

DESCRIPTION

JUSTIFICATION

Fully Conforms to Material Type X outlined in the standard

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical I

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-219	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical I

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ASTM F136	ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vana	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
None.

DESCRIPTION

JUSTIFICATION
Fully Conformed.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F648 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Impla

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-208	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F648 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Impla

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ASTM F648	Standard Specification for Ultra-High-Molecular-Weight Polyeth	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
None.

DESCRIPTION

JUSTIFICATION
Fully Conformed.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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December 17, 2013

TRUTHFUL AND ACCURATE STATEMENT

As required by 21 CFR 807.87(k)

I certify that, in my capacity as Project Manager, Regulatory Affairs of Wright Medical Technology, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Matt Paul, MSc
Project Manager, Regulatory Affairs

December 17, 2013

CLASS III CERTIFICATION AND SUMMARY

As Required by 21 CFR 807.94

This section is not applicable.

012. Traditional 510(k) Premarket Notification

DYNASTY® Acetabular System with Ceramic

I. MANUFACTURER IDENTIFICATION

Manufacturer's Name:	**Wright Medical Technology, Inc.** 5677 Airline Road Arlington, TN 38002
Establishment Registration Number:	**1043534**
Primary Contact:	**Matt Paul** Project Manager, Regulatory Affairs **Phone:** 901-867-4350 **Fax:** 901-867-4190
Secondary Contact:	**Theresa Leister** Manager, Regulatory Affairs **Phone:** 901-867-5898 **Fax:** 901-867-4190

II. SUBJECT DEVICE IDENTIFICATION

Proprietary Name:

DYNASTY® Shell,
DYNASTY® A-CLASS® Crosslinked Poly Liner,
BIOLOX® DELTA Femoral Head

Common Name:	Acetabular Shell, Liner, Femoral Head
Classification Name and Reference:	888.3353 Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented – Class II
Subject Product Code and Panel Code:	Orthopedics/87/ LZO

III. PREDICATE DEVICE IDENTIFICATION

Predicate Proprietary Name, Classification/Number, Product and Panel Codes:

Shell:	Model number 36510046	**LINEAGE® Acetabular System** 888.3358 Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented – Class II Orthopedics/87/LPH **(K002149)**

Liner:	Model numbers 364128X1, 364528X1	**LINEAGE® Acetabular System** 888.3353 Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented – Class II Orthopedics/87/LZO **(K052026)** 888.3358 Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented – Class II Orthopedics/87/LPH **(K052026)** 888.3350 Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented – Class II Orthopedics/87/JDI **(K052026)**
Head:	Model number PHA04408	**DYNASTY® Acetabular System** 888.3353 Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented – Class II Orthopedics/87/LZO **(K130376)**

IV. DEVICE DESCRIPTION

The subject devices of this Traditional 510(k) include two modular DYNASTY® Acetabular Shells, two DYNASTY® A-CLASS® Poly Acetabular Liners, and three ceramic composite BIOLOX® DELTA Femoral Heads. Predicate shells and liners were cleared with the LINEAGE® Acetabular System. Applicable testing of locking acetabular components was submitted with the predecessor LINEAGE® Acetabular System. Predicate femoral heads were cleared with the DYNASTY® Acetabular System. Special controls of FDA Guidance Documents are not available for the subject devices. Special controls of industry standards are included in the **Tab 002 CDRH Cover Sheet**.

The Part List is contained in **Tab 023 Exhibit 01**. Subject Device Drawings are contained in **024 Exhibit 02**. Instruments for the subject devices are described in **017 Biocompatibility**.

Sizing

The subject devices are two DYNASTY® Acetabular Shells available in smaller sizes (Group B 46 and 48mm outside diameters), intended for use with the subject polyethylene liners. Either shell size Group B is compatible with either subject liner of size Group B.

Part Numbers:
Shells
DSPCGB46
DSPCGB48

The subject devices are DYNASTY® A-CLASS® Poly Acetabular Liners in a smaller size 28mm bearing, available with or without a protruding hemispherical rim lip (pictured). These liners are intended for use with the subject 28mm ceramic composite heads. Either size Group B liner can mate with a DYNASTY® size Group B shell.

Liners
DLXPGB28
DLXPLB28

BIOLOX® DELTA Femoral Heads were originally cleared in K130376 in diameter sizes 32, 36 and 40 mm for use with DYNASTY® A-CLASS® Poly Liners. The subject devices are the BIOLOX® DELTA Ceramic Femoral Heads sizes 28mm, intended for use with the subject DYNASTY® A-CLASS® Poly Liners, size 28mm. The subject heads are available in a short, medium and long bore offset intended to assemble with Wright femoral stems.

DELTA Heads
PHA04402
PHA04404
PHA04406

(b)(4)Trade Secret Process

[redacted]

Materials

The subject DYNASTY® Acetabular Shells are manufactured from titanium alloy (Wrought Titanium-6Aluminum-4Vanadium) conforming to ASTM F136, identical to the predicate in K002149. The commercially pure titanium (ASTM F67) bead coating material and process are identical to the cleared predicate.

DYNASTY® A-CLASS® Poly Acetabular Liners are manufactured from cross-linked ultra-high-molecular-weight polyethylene (UHMWPE) conforming to ASTM F648, identical to the similar sized predicates in K052026.

BIOLOX® DELTA Femoral Heads are manufactured from alumina composite conforming to ISO 6474-2, identical to the predicate in K130376. The heads are supplied complete in form by (b)(4)Trade Secret Process [redacted] authorization letter to the Master File is in tab section **036 Exhibit 08**). Previous clearance information is listed in Table 1, as required by FDA Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems. Wright possesses a clearance for larger sizes, but no PMA is approved for these components. Further information to address this guidance is detailed in the following sections.

Table 1. Clearance information for subject BIOLOX® DELTA Femoral Heads.

Document Number	Title/Company	Sizing
(b)(4)Trade Secret Process [redacted]		28-40mm
K071535	Biolox Delta Ceramic Femoral Head / Zimmer, Inc.	28-40mm
K082996	Biolox Delta Option Ceramic Heads / Biomet, Inc.	28-40mm
K083762	Biolox Delta Ceramic Femoral Heads / Smith & Nephew, Inc.	28-36mm
K100412	Biolox Delta Ceramic Femoral Heads / Smith & Nephew, Inc.	40-44mm
K130376	Wright Biolox Delta Femoral Heads	32-40mm

Compatible Devices

The subject components are intended for use with each other. Liners mate with shells sharing the same size Group, as described within the surgical technique labeling. The available combinations for the subject heads, liners and shells are listed in Table 2.

Table 2. Compatibility among the subject components.

Femoral Heads	Compatible Liners	Compatible Shells
BIOLOX® DELTA Femoral Heads – 28 mm • Subject heads	DYNASTY® A-CLASS® Poly Liners – 28 mm • Subject liners	DYNASTY® Shells, Group B: • Subject shells • K082924 shells • K122382 shells

The shell clearances cited in Table 2 are described in greater detail in Table 3. These shell types were cleared in K130376 for use with larger diameter BIOLOX® DELTA ceramic-polyethylene bearings.

Table 3. Compatible Shells, Including 510(k) Information

510(k)	Device Name	Shell Material	Cemented/ Cementless	Previous Classification
K122382	DYNASTY® 10 Hole Revision Shells	ASTM F620	Cementless	MBL JDI LZO
K122382	DYNASTY® BIOFOAM® 3-Hole Quadrant Shells	ASTM F620	Cementless	MBL JDI LZO
K122382	DYNASTY® BIOFOAM® Solid Shells	ASTM F620	Cementless	MBL JDI LZO
K122382	DYNASTY® BIOFOAM® 5 Hole Shells	ASTM F620	Cementless	MBL JDI LZO
K082924	DYNASTY® BIOFOAM® Shells	ASTM F620	Cementless	KWA JDL

The subject DYNASTY® Acetabular System is indicated to be paired with the femoral components in Table 4 below. Per the Ceramic Ball Hip guidance, material standard number and cementation are included in the table. Clearance letters are included in tab section **026 Exhibit 04**. All ceramic head model numbers included in **Tab 023 Exhibit 01** are for use with these stems. The taper cone length, angle, diameter, straightness, and surface roughness are identical for these compatible components. For these femoral trunnions, there are only 4 material types Wright manufactures for the US, all of which are compatible with the subject BIOLOX® DELTA Femoral Heads:

- Wright 12/14 SLT taper Wrought Ti alloy ASTM F136
- Wright 12/14 SLT taper Forged Ti alloy ASTM F620
- Wright 12/14 SLT taper Forged CoCr ASTM F799
- Wright 12/14 SLT taper Wrought CoCr ASTM F1537 Type 2

The length [redacted] angle [redacted] diameter [redacted] straightness [redacted] and surface roughness [redacted] are all identical for the four tapers. All of the compatible stems and modular necks employ one of these four tapers. All noted tests evaluate these tapers. Bore length, straightness, surface roughness, and length of ball/cone overlap for the subject heads is provided in Table 5. Stem trunnion and machined grooves specification are depicted below.

Wright Trunnion Specification

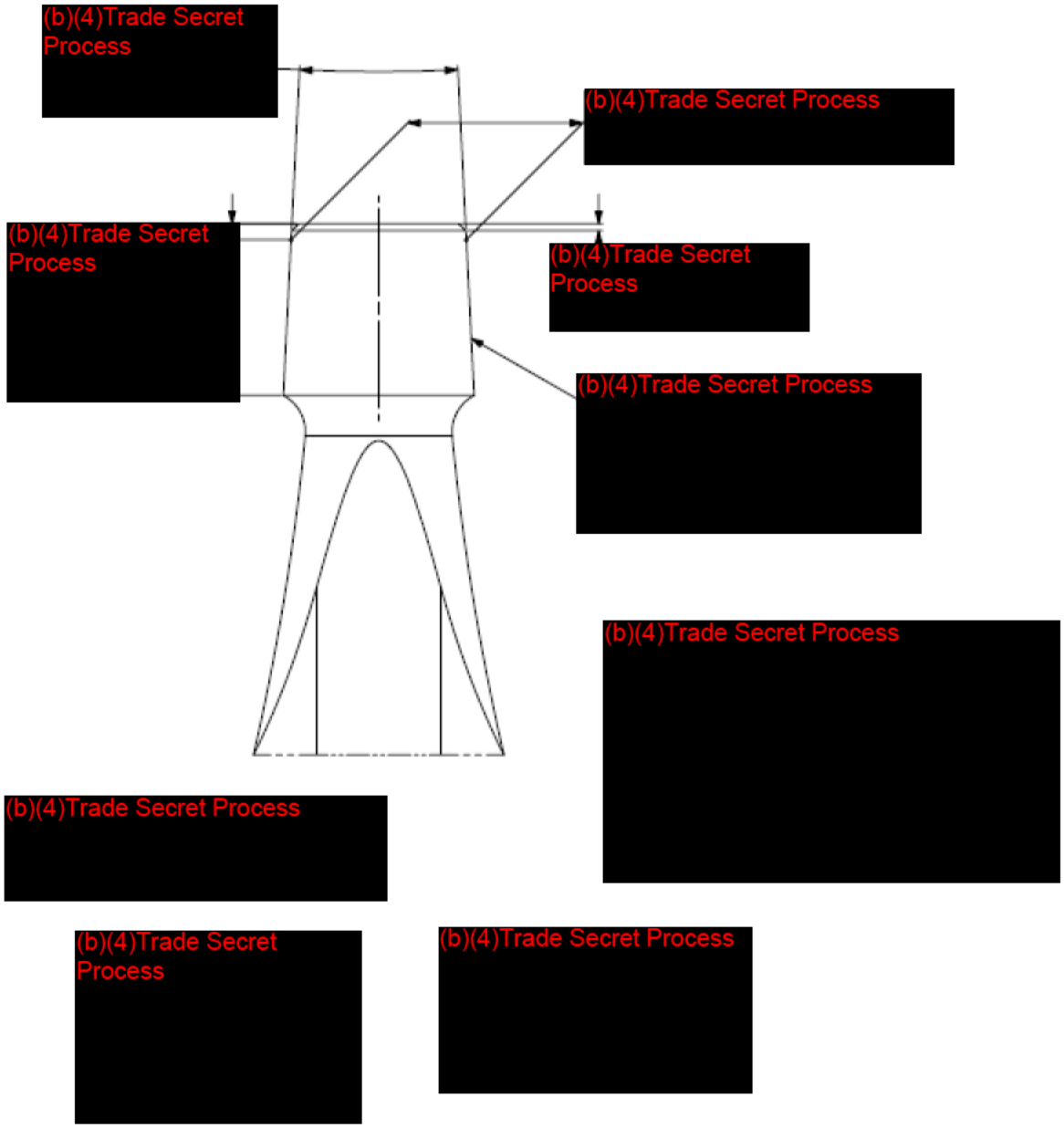

Table 4. Compatible Femoral Components, Including 510(k) Information

510(k)	Device Name	*Indications for use	Neck Configuration	Stem Material	Cone Material
K003016	PRO-FEMUR R	Cementless	Mod Neck	(b)(4)Trade Secret Process [redacted]	
K012091	PRO-FEMUR	Cementless	Mod Neck		
K021346	STEM HIP REPLACEMENT SYSTEM	Cementless	Mod Neck		
K041114	PROFEMUR TAPERED HIP STEM	Cementless	Mod Neck		
K041586	PROFEMUR S HIP STEM	Cementless	Mod Neck		
K051995	PROFEMUR RENAISSANCE HIP STEM	Cementless	Mod Neck		
K052915	PROFEMUR XTR HIP STEM	Cemented	Mod Neck		
K053588	PROFEMUR LX HIP STEM	Cementless	Mod Neck		
K060358	PROFEMUR TL HIP STEM	Cementless	Mod Neck		
K080663	PROFEMUR LX REVISION 5/8 COATED HIP STEM	Cementless	Mod Neck		
K081090	PROFEMUR LX 5/8 COATED HIP STEM	Cementless	Mod Neck		
K091423 K100866	PROFEMUR HIP SYSTEM MODULAR NECKS	Cementless	Mod Neck		
K110399	GLADIATOR PLASMA CLASSIC HIP STEM	Cementless	Fixed Neck		
K111698	PROFEMUR(R) E CEMENTLESS HIP STEM	Cementless	Mod Neck		

K111699	PROFEMUR(R) Z TITANIUM PLASMA SPRAYED HIP STEM	Cementless	Mod Neck	(b)(4)Trade Secret Process [redacted]
K111910	GLADIATOR HIP STEM	·Cementless/ ·Cemented	Mod Neck	
K112080	PRESERVE HIP STEM	Cementless	Mod Neck	
K112150	PROFEMUR GLADIATOR HA HIP STEM	Cementless	Mod Neck	
K121221	PROFEMUR Z REVISION HIP STEM	Cementless	Mod Neck	
K123434	PROFEMUR Z CLASSIC STEM	Cementless	Fixed Neck	
K123688	PROFEMUR TL CLASSIC STEM	Cementless	Fixed Neck	
K130984	PROFEMUR RENAISSANCE CLASSIC STEM	Cementless	Fixed Neck	

Note: All stems except K130984 were recently cleared for a BIOLOX® DELTA ceramic-polyethylene bearing in K130376.

Table 5: Ball/Cone Overlap and Bore Dimensions for Subject Ceramic Heads

Part Number	Description	Bore Length (mm)	Overlap (mm)	Percent Overlap (%)	Bore Length (mm)	Bore Straightness (mm)	Bore Surface Roughness Ra (µm)
BIOLOX® DELTA Femoral Heads							
PHA04402	28 mm Short	(b)(4)Trade Secret Process [redacted]					
PHA04404	28 mm Med						
PHA04406	28 mm Long						

(b)(4)Trade Secret Process [redacted]

The design features of the subject devices are substantially equivalent to those of the predicate LINEAGE® and DYNASTY® Acetabular system devices cleared under K002149, K052026 and K130376, respectively. The indications of the subject device are identical to the predicate, respectively. Specific warnings appear in the package insert as cleared in K130376. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the DYNASTY® Acetabular System is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

V. COMPARISON TO CLEARED PREDICATE

The indications for use remain unchanged for the subject devices compared to the predicate device K130376, as listed in Table 6. The K002149 LINEAGE® Acetabular System possessed an additional indication and was intended for uncemented use only.

The material bearing use of the subject devices are the same as the predicate K130376. Therefore, there is no change in intended use. Refer to Section II Subject Device Identification on page 1 for the associated product codes, regulation and classification of the subject devices.

Table 6. Comparison of indications for use for subject devices compared to the predicate devices.

	Subject Devices	**K130376 DYNASTY® Acetabular System (Heads predicate)**	**K052026 LINEAGE® Acetabular System (Liners predicate)**	**K002149 LINEAGE® Acetabular System (Shells predicate)**
Indications for Use	Wright total hip systems **are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.** **Indications for Use** **1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;** **2) inflammatory degenerative joint disease such as rheumatoid arthritis;** **3) correction of functional deformity; and,** **4) revision procedures where other treatments or devices have failed.** Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty. Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.	Wright total hip systems **are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.** **Indications for Use** **1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;** **2) inflammatory degenerative joint disease such as rheumatoid arthritis;** **3) correction of functional deformity; and,** **4) revision procedures where other treatments or devices have failed.** Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty. Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.	**Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:** **1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;** **2) inflammatory degenerative joint disease such as rheumatoid arthritis;** **3) correction of functional deformity; and,** **4) revision procedures where other treatments or devices have failed.** **Cleared in K052026 for both cemented and uncemented classifications. (Shells may be either. Liners are assembled to shells without cement.)**	**Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:** **1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;** **2) inflammatory degenerative joint disease such as rheumatoid arthritis;** **3) correction of functional deformity;** **4) revision procedures where other treatments or devices have failed; and,** **5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.** The LINEAGE® Acetabular System are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of an **uncemented** total hip arthroplasty.

A. SUBJECT DYNASTY® ACETABULAR SHELLS

Aside from dimensional changes, the subject DYNASTY® Acetabular Shells are identical to the predicate shells in material, coating, fixation features and assembly lock detail. Subject and predicate drawings are presented in **Tab 024 Exhibit 02** and **Tab 025 Exhibit 03**, respectively. Table 7 provides a comparison to the predicates.

Table 7. Comparison of subject DYNASTY® Shells to predicate DYNASTY ® and LINEAGE® Shells

Features	Subject Devices	Predicate Device (K002149)
Size Group (Inner Dimensions)	DYNASTY® Group B 46, 48 mm	LINEAGE® Group 1 46, 48mm
Shell Material	Titanium Alloy (b)(4)Trade	Titanium Alloy (b)(4)Trade
Liner Material	Polyethylene	Polyethylene
Surface Coating	Titanium Beads (b)(4)Trade	Titanium Beads (b)(4)Trade
Liner Lock Detail	Interrupted 6-Leaf Clover	Interrupted 6-Leaf Clover
Impactor Dome Thread	Yes	Yes
Screw Fixation	3 holes in a single quadrant	3 holes in a single quadrant

(b)(4)Trade Secret Process [redacted] Table 8 below details the worst-case thicknesses of the subject and predicate devices, with the worst-case values in bold for comparison. Thus, the subject shells do not introduce a new worst-case to the DYNASTY® Acetabular Shell family.

Table 8. Critical thickness of subject DYNASTY® Acetabular Shells to predicate LINEAGE® Acetabular Shell (K002149)

Shell Size	Part Number	Regions of Critical Thickness (in.)		
Subject Shell		Rim	Dome	Loading
Dynasty® Group B 46mm	DSPCGB46	(b)(4)Trade Secret Process [redacted]		
Dynasty™ Group B 48mm	DSPCGB48			
Predicate Shell				
LINEAGE® Group 1 46mm (K002149)	36510046			

B. SUBJECT DYNASTY® A-CLASS® POLY ACETABULAR LINERS

The subject DYNASTY® A-CLASS® Poly Acetabular Liners are identical to the predicate liners in material, surface finish and liner lock position. Subject and predicate drawings are presented in **Tab 024 Exhibit 02** and **Tab 025 Exhibit 03**, respectively. Table 9 provides a high level comparison to the predicate.

Table 9. Comparison of subject DYNASTY® A-CLASS® Poly Acetabular Liners to predicate DYNASTY® and LINEAGE® A-CLASS® Poly Acetabular Liners (K052026)

Features	Subject Devices	Predicate Devices (K052026)
Sizes (Inner Diameter)	28mm	28mm
Liner Material	UHMWPE – (b)(4)Trade Secret [redacted] Process	
Surface Finish	R_a 35 µin. max	
Liner Lock Positions	360° Continuous	

The subject liner is available in both an unlipped (0°) and a lipped (15°) variety. The lip feature consists of an extrusion of material, which extends distally from the liner rim around half its circumference. The raised lip extends 15° (from center) above the plane of the liner rim. This lip feature has precedent in the predicate LINEAGE® A-CLASS® Poly Liner (K052026). The lip of the subject liner is thicker than the lip of the predicate liner.

The two subject liners are identical worst cases, with the exception of the 15° lip, which reduces maximum range of motion by 15°. Likewise, the predicate 28mm LINEAGE® liners consisted of a lipped and unlipped version, both cleared in K052026.
For polyethylene liners, regarding fatigue and disassociation risks the following dimensions must be equal to or greater than those of the predicate device:

1) Material must be identical or equivalent
2) The thickness of the subject liners in four critical areas (rim, taper, loading point, dome)
3) Lock detail surface area
4) Tolerances/material interaction with shell

The worst case of the two liner part numbers (lipped liner DLXPLB28) fulfills these requirements as follows, with respect to the predicate LINEAGE® Group 1 Lipped 28mm liner (364528X1, cleared in K052026):

1. Material is identical to the predicate
2. The thickness of the subject liners in four critical areas (rim, taper, loading point, dome) is greater than that of the predicate (Table 10)
3. Lock detail surface area is greater than that of the predicate (Table 10)

4. All other tolerances/material interactions with the shell are equal to or tighter tolerances than the predicate (Summary of Design Control Activities table)

Therefore, fatigue and disassociation testing performed on the predicate K052026 is applicable to the subject liners.

Table 10 below details the thicknesses of the subject and predicate devices in the four critical zones, with the worst-case values for both the previous and new product generations in bold for comparison. Additionally, the surface area of the lock detail is greater than that of the predicate devices. Thus, the subject liners do not introduce a new worst-case to the DYNASTY® A-CLASS® Poly Acetabular Liner family in terms of fatigue or disassociation.

Table 10. Critical thickness of subject DYNASTY® A-CLASS® Poly Acetabular Liners to predicate LINEAGE® A-CLASS® Poly Acetabular Liners (K052026)

	Part Number	**Diameter Size**	**Regions of Thickness (in.)**				**Lock Detail Surface Area (in^2)**
	Subject Liners		Rim	Taper	Loading	Dome	
	DLXPGB28	28 mm	(b)(4)Trade Secret Process [redacted]				
	DLXPLB28	28 mm					
	Predicate Liners						
K052026	364128X1	28mm					

Range of motion for the subject devices when paired with the subject femoral heads is detailed in Table 11. Minimum values remain in conformance with ISO 21535 and are greater than the predicate LINEAGE® A-CLASS® Poly Acetabular Liners (K052026).

Table 11. Minimum range of motion comparison of subject DYNASTY® A-CLASS® Poly Acetabular Liners to predicate LINEAGE® A-CLASS® Poly Acetabular Liners (K052026)

	Part Number	Abduction/ Adduction	Flexion/ Extension	Internal/ External Rotation
ISO 21535 Minimum Range of Motion	**-**	**60°**	**100°**	**90°**
Subject Worst Case Liner Dynasty® Group B 28mm 15° Lipped	DLXPLB28	(b)(4)Trade Secret Process [redacted]		
Predicate Liner LINEAGE® A-CLASS® Group 1 28mm 15° Lipped (K052026)	364528X1			

Bearing characteristics for the subject liners are identical to the predicate liners (K052026) regarding material, diameter, sphericity tolerance and surface finish. Wear testing of the subject 28mm liners and heads was provided in K130376 to clear larger diameter sizes reviewed in that filing, as noted in the following section and provided in **Tab 028 Exhibit 05.**

C. SUBJECT BIOLOX® DELTA Femoral Heads

The subject heads supplied by (b)(4)Trade Secret were cleared for competitors in several 510(k)'s listed above in Table 1. Aside from dimensional changes, the subject ceramic head size is identical to the predicate ceramic femoral head sizes (K130376) in all other aspects of the design. Subject and predicate drawings are presented in **Tab 024 Exhibit 02** and **Tab 025 Exhibit 03**, respectively.

Mating bore angle and surface characteristics are identical to the predicate sizes. The material, bearing sphericity tolerance and surface finish tolerances for the subject femoral heads are identical to those of the predicate femoral heads. Table 12 provides a comparison to the predicate. The subject size 28mm head was used as a worst case in burst, post-fatigue burst, rotational stability, pull off force testing, and wear testing. Results of all mechanical tests met the requirements according to (b)(4)Trade procedure and the FDA Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems. This testing was previously submitted and applied to the larger sizes cleared in K130376, and is provided again as **Exhibit 05 (Tab Sections 027** and **028)**. Therefore the subject heads, as tested, have demonstrated adequate material properties.

Table 12. Comparison of subject 28mm BIOLOX® DELTA Femoral Heads to predicate 32mm BIOLOX® DELTA Femoral Heads (K130376).

Features	Subject Devices	Predicate Devices (K130376)
Sizes (Outer Diameter)	28 mm	32, 36, 40 mm
Head Material	Alumina Composite – (b)(4)	Alumina Composite – (b)(4)
Vendor Manufacturer	(b)(4)Trade	(b)(4)Trade
Taper Type (angle, roughness, straightness, sphericity)	SLT	SLT
Bearing Surface: **Roughness** **Sphericity** **Diametral Tolerances**	(b)(4)Trade Secret Process	
Taper Length	28mm Short 28mm Medium 28mm Long (b)(4)Trade Secret Process	32mm Short 32mm Medium 32mm Long (b)(4)Trade Secret Process

SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject devices include only dimensional changes compared to the predicate devices. No changes occur in fundamental scientific technology, intended use, indications, material, or sterilization for the subject devices compared to the predicate devices. Indications for the subject devices are found in the submission behind **Tab 008** 510(k) Summary and **Tab 007** Indications for Use Statement. Detailed comparisons between the subject and predicate devices with respect to technology and performance specification are discussed in detail and can be found located behind **Tab 012** Premarket Notification. The dimensional changes do not present a new-worst case that necessitate mechanical testing. Thus, testing of the predicate devices remains applicable to the subject devices. Testing rationales are included in the submission behind **Tab 020** Performance Testing – Bench, and full test reports in **Tab 027** and **028**.

The subject devices are substantially equivalent to the predicate devices.

FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

This section does not apply.

Proposed Labeling

Labeling for the subject DYNASTY® Acetabular System can be found in **Exhibit 07 (Tabs 032-035)**. These include a draft package insert, sample labels, a draft surgical technique, and the legend for the packaging symbols that will be placed on the outer carton to satisfy ODE labeling requirements.

The package insert for the subject devices, included in **Tab 035 Exhibit 07**, was cleared in K130376 and will be implemented for these devices as a running change. No changes to this package insert are necessary for the subject devices, including the intended use. Products noted within quotation marks are described exactly as they appear on the package label.

Example labels are included in **Tab 032 Exhibit 07**.

The subject devices may also be implanted with instruments for alternative surgical approaches, as cleared in K102565, K121221, and K122382.

Regarding allowable device combinations, the labeling (package insert and surgical technique) clarify the compatible stem components for use with the subject ceramic heads as follows.

- The subject heads are compatible with all cleared stems, with only one exception. This exception, the historical Orthomet taper, is described in the final paragraph of the package insert, specifying exclusive compatibility between head and stem components possessing the Orthomet design. Additionally, the package labels for the subject BIOLOX® Delta ceramic heads clearly state that these components possess the SLT taper.
- The list of compatible acetabular liner and shell components for use with the subject BIOLOX® Delta ceramic heads is detailed beginning on page 9 of the surgical technique included as tab section **Tab 034 Exhibit 07.**

Also provided is a copy of the proposed surgical technique (**034 Exhibit 07**). Instruments used with the system are identical to ones for the predicate system K130376, except for the addition of a small number of instruments specifically dimensioned for the subject implant sizes. They are listed and categorized as either General or Specialized in the surgical technique.

Sterilization and Shelf Life

The DYNASTY® Acetabular Shell and BIOLOX® DELTA Femoral Heads are sterilized using Gamma Radiation, which is identical to predicate shells, heads and sleeves. A Gamma Radiation Sterilization Summary is provided in **029 Exhibit 06**. The applicable validation report for BIOLOX® DELTA Femoral Heads is included, as cleared in K130376.

The DYNASTY® A-CLASS® Poly Acetabular Liners are sterilized using Ethylene Oxide, which is identical to predicate liners and heads. An Ethylene Oxide Sterilization Summary is provided in **Tab 030 Exhibit 06**. The subject devices do not present a new worst-case scenario based on product, density, size and worst-case for EtO sterilization. Since the subject devices are manufactured from the same material and possess the same double barrier sterile packaging, therefore the residuals and tolerable contact limits (TCL) demonstrated in **030 Exhibit 06** are applicable to the subject devices.

Instruments are provided nonsterile, intended for customer steam sterilization. Wright has previously provided validation for the cleaning/sterilization of instruments in previous reviews (K122218). This validation was performed using the overkill method and completed according to validation standard AAMI TIR 12.

Packaging for the subject devices consists of either a PETG thermoformed tray with Tyvek lid heat sealed to the tray and placed inside a second PETG tray with Tyvek lid or a poly Tyvek pouch sealed and placed inside a second poly Tyvek pouch. The trays or pouches are inserted into a paperboard carton that is shrink wrapped. The shelf life for this packaging configuration is set at 8 years. The shelf life validation study and packaging integrity characterization are summarized and provided in the attached document (b)(4)Trade Secret in **Tab 031 Exhibit 06**.

Biocompatibility

Implants
All subject devices are permanently implanted. The subject devices are composed of materials identical to the predicate devices.

The subject DYNASTY® Acetabular Shells are manufactured from titianium alloy (b)(4)Trade Secret [redacted] conforming to (b)(4)Trade Secret [redacted] identical to the predicate in K002149. The commercially pure titanium (b)(4)Trade Secret [redacted] bead coating material and process are identical to the cleared predicate. The shells contain no color additives. Thus, biocompatibility testing is not necessary for the subject devices.

DYNASTY® A-CLASS® Poly Acetabular Liners are manufactured from cross-linked ultra-high-molecular-weight polyethylene (UHMWPE) conforming to (b)(4)Trade Secret [redacted] identical to the similar sized predicates in K052026. The liners contain no color additives. Thus, biocompatibility testing is not necessary for the subject devices.

BIOLOX® DELTA Femoral Heads are manufactured from alumina composite conforming to (b)(4)Trade Secret [redacted], identical to the predicate in K130376, and made of (b)(4)Trade Secret [redacted] alumina matrix composite containing Zirconia grains (b)(4)Trade Secret [redacted] and strontium-platelets. Biocompatibility testing and color additives information for these vended products (b)(4)Trade Secret [redacted]) are identical to the predicate sizes cleared in K130376. Thus, further biocompatibility testing is not necessary for the subject devices.

Instruments
A list of patient-contacting instruments, previously cleared under K122382, is listed below and in the Surgical Technique, **Tab 034 Exhibit 07**. All instruments are the same except for the addition of new sizes of trials for subject shells, liners, heads and neck sleeves to allow a mock component assembly before final implantation of the subject implants. (Trial liners or heads do not exist for the 44mm and 48mm sizes.) These trial instruments are manufactured from identical materials already cleared.

Instrument Biocompatibility Assessment

All instruments contained within the list below are intended for temporary patient contact to be limited to time required for surgery. The materials list below, and biocompatibility information, has not changed since the previous clearance under K122382; therefore, no new biocompatibility testing is deemed necessary.

Instrument Kit Parts List ***Cleared under K122382***		
Item Number	Description	Material
DNFLKIT1		
General		
33330002	DYNASTY® SCREWDRIVER	Stainless Steel ASTM A564 Type 630
Specialized		
3300GB46	DYNASTY® TRIAL SHELL GROUP B 46MM OD	ASTM F136 Titanium
3300GB48	DYNASTY® TRIAL SHELL GROUP B 48MM OD	ASTM F136 Titanium
3300GC50	DYNASTY® TRIAL SHELL GROUP C 50MM OD	ASTM F136 Titanium
3300GD52	DYNASTY® TRIAL SHELL GROUP D 52MM OD	ASTM F136 Titanium

3300GE54	DYNASTY® TRIAL SHELL GROUP E 54MM OD	ASTM F136 Titanium
3300GF56	DYNASTY® TRIAL SHELL GROUP F 56MM OD	ASTM F136 Titanium
3300GG58	DYNASTY® TRIAL SHELL GROUP G 58MM OD	ASTM F136 Titanium
3300GG60	DYNASTY® TRIAL SHELL GROUP G 60MM OD	ASTM F136 Titanium
41102800	DYNASTY® HEAD TRIAL 28MM	Radel R5500
41103200	DYNASTY® HEAD TRIAL 32MM	Radel R5500
41103600	CONSERVE® TOTAL HEAD TRIAL 36MM	Radel R5500
41104000	CONSERVE® TOTAL HEAD TRIAL 40MM	Radel R5500
33330010	DYNASTY® SHELL IMPACTOR STRAIGHT OVERMOLD	ASTM A564 Type 630 Stainless Steel
33330020	DYNASTY® LINER IMPACTOR STRAIGHT OVERMOLD	Stainless Steel ASTM A564 Type 630
33330040	DYNASTY® LINER IMPACTOR CURVED OVERMOLD	Stainless Steel ASTM A564 Type 631
33330046	DYNASTY® LINER EXTRACTOR GROUP B 46-48MM OD	UNS S13800
33330050	DYNASTY® LINER EXTRACTOR GROUP C 50MM OD	UNS S13800
33330052	DYNASTY® LINER EXTRACTOR GROUP D 52MM OD	UNS S13800
33330054	DYNASTY® LINER EXTRACTOR GROUP E 54MM OD	UNS S13800
33330056	DYNASTY® LINER EXTRACTOR GROUP F 56MM OD	UNS S13800
33330058	DYNASTY® LINER EXTRACTOR GROUP G 58MM OD	UNS S13800
33330064	DYNASTY® LINER EXTRACTOR GROUP H 64-66-68MM OD	UNS S13800
33330015	DYNASTY® TRIAL HEAD IMPACTOR	Stainless Steel ASTM A564 Type 630
DNALTRA1	DYNASTY® ALPHA TRAY	Aluminum
DNFLTRA1	DYNASTY® FULL LAUNCH TRAY	Aluminum
3304GB28	DYNASTY® STD POLY TRIAL LINER GROUP B 28MM	Polypropylene
3304GC32	DYNASTY® STD POLY TRIAL LINER GROUP C 32MM	Polypropylene
3304GD36	DYNASTY® STD POLY TRIAL LINER GROUP D 36MM	Polypropylene
3304GF40	DYNASTY® STD POLY TRIAL LINER GROUP F 40MM	Polypropylene
3304LB28	DYNASTY® 15DG POLY TRIAL LINER GROUP B 28MM	Polypropylene
3304LC32	DYNASTY® 15DG POLY TRIAL LINER GROUP C 32MM	Polypropylene
3304LD36	DYNASTY® 15DG POLY TRIAL LINER GROUP D 36MM	Polypropylene
3304LF40	DYNASTY® 15DG POLY TRIAL LINER GROUP F 40MM	Polypropylene
33330001	DYNASTY® TRIAL LINER SCREW	Stainless Steel ASTM A564 Type 630
33330080	DYNASTY® ALIGNMENT GUIDE STRAIGHT HANDLE 20 DEGREE	Stainless Steel ASTM A564 Type 630
33330085	DYNASTY® ALIGNMENT GUIDE CURVED HANDLE 20 DEGREE	Stainless Steel ASTM A564 Type 630
3300GG62V1	V1 DYNASTY® TRIAL SHELL GROUP G 62MM OD	ASTM F136 Titanium
3300GH64V1	V1 DYNASTY® TRIAL SHELL GROUP H 64MM OD	ASTM F136 Titanium
3300GH66V1	V1 DYNASTY® TRIAL SHELL GROUP H 66MM OD	ASTM F136 Titanium
3300GH68V1	V1 DYNASTY® TRIAL SHELL GROUP H 68MM OD	ASTM F136 Titanium
DNFLKIT2		
Item Number	Description	Material

Specialized		
3300GJ70	DYNASTY® TRIAL SHELL GROUP J 70MM OD	ASTM F136 Titanium
3300GJ72	DYNASTY® TRIAL SHELL GROUP J 72MM OD	ASTM F136 Titanium
3300GJ74	DYNASTY® TRIAL SHELL GROUP J 74MM OD	ASTM F136 Titanium
3300GK76	DYNASTY® TRIAL SHELL GROUP K 76MM OD	ASTM F136 Titanium
3304GJ50	DYNASTY® STD POLY TRIAL GROUP J 50MM ID	ASTM F136 Titanium
3304GK54	DYNASTY® STD POLY TRIAL GROUP K 54MM ID	ASTM F136 Titanium
3304LJ50	DYNASTY® 15DG POLY TRIAL GROUP J 50MM ID	Polypropylene
3304LK54	DYNASTY® 15DG POLY TRIAL GROUP K 54MM ID	Polypropylene
33330070	DYNASTY® LINER EXTRACTOR GROUP J 70-74MM OD	Stainless Steel ASTM A564Type XM-21
33330076	DYNASTY® LINER EXTRACTOR GROUP K 76MM OD	Stainless Steel ASTM A564Type XM-21
8400KIT1		
Item Number	Description	Material
General		
8400FD04	F LEX DRILL BIT 3.2 X 15MM	(Teflon) T2282 (DIN 1.4034) ASTM A581
8400FD05	FLEX DRILL BIT 3.2 X 25MM	(Teflon) T2282 (DIN 1.4034) ASTM A581
8400FD06	FLEX DRILL BIT 3.2 X 35MM	(Teflon) T2282 (DIN 1.4034) ASTM A581
8400FD07	FLEX DRILL BIT 4.5 X 15MM	(Teflon) T2282 (DIN 1.4034) ASTM A581
8400FD08	FLEX DRILL BIT 4.5 X 25MM	(Teflon) T2282 (DIN 1.4034) ASTM A581
8400FD09	FLEX DRILL BIT 4.5 X 35MM	(Teflon) T2282 (DIN 1.4034) ASTM A581
8400FD10	FLEX DRILL BIT 4.5 X 45MM	(Teflon) T2282 (DIN 1.4034) ASTM A581
8400SD02	HEX HEAD SCREWDRIVER BIT MODULAR	(Teflon) T1962 (ASTM A167, DIN 1.4034, DIN 1.4112)
8400SD03	UNIVERSAL JOINT 3.5MM HEX DRIVER SHFT W/STRYKER FIT	(Teflon) T2310 (ASTM A167, ASTM A581, DIN 1.4034)
8400SD04	BALL & SOCKET 3.5MM HEX DRVR SHFT STR SOL W/STRYK	ASTM A564 Type 630
8400SD06	HEX DRIVER SHAFT W/STRYKR STRAIGHT SOLID 3.5MM	(Teflon) T2522 (ASTM A167, DIN 1.4034)
8400ST01	SCREW TAP MODULAR 6.5 X 15MM	(Teflon) T2279 (DIN 1.4034) ASTM A581
8400ST02	SCREW TAP MODULAR 6.5 X 25MM	(Teflon) T2279 (DIN 1.4034) ASTM A581
8400ST03	SCREW TAP MODULAR 6.5 X 35MM	(Teflon) T2279 (DIN 1.4034) ASTM A581
2002QCRH	QUICK CONNECT RACHET HANDLE	Stainless Steel ASTM A276 Type 440C, ASTM A564 Type 630, 6061-T6511 Al, ASTM D2000 GE 605Z1 (silicone), ASTM A564 Type 630
Specialized		

4820SH0000	00 INTERSEAL® SCREW HOLDER	Stainless Steel ASTM A564 Type 630
8400DG01	LINEAGE® FIXED ANGLE DRILL GUIDE 3.2mm/4.5mm	Stainless Steel ASTM A564 Type 630
8400DG03	ADJUSTABLE DRILL GUIDE	(Teflon) T2278 (DIN 1.4034 e T2398 ASTM A581, ASTM A105, ASTM A580)
8400FD01	FLEXIBLE DRILL SCREW SHAFT MODULAR	Stainless Steel ASTM A564 Type 630
8400FD02	FLEX DRILL 3.2 X 25MM ONE PIECE	Precimed (Teflon)
8400FD03	FLEX DRILL 4.5 X 25MM ONE PIECE	(Teflon) T2278 (DIN 1.4034 T2398 ASTM A581, ASTM A105, ASTM A580)
8400SG01	ADJUSTABLE SCREW DEPTH GAUGE	ASTM A564 Type 630
84003000	LINEAGE® ACETABULAR SCREW INSTRUMENT CASE	Stainless Steel ASTM A564 Type 630
2001KIT5		
Item Number	Description	Material
Specialized		
20010400	ACETABULAR REAMER HANDLE PRECIMED® DESIGN	Stainless Steel ASTM A564 Type 630
20010441	ACETABULAR REAMER PRECIMED® DESIGN 41mm	Stainless Steel ASTM A564 Type 630
20010442	ACETABULAR REAMER PRECIMED® DESIGN 42mm	Stainless Steel ASTM A564 Type 630
20010443	ACETABULAR REAMER PRECIMED® DESIGN 43mm	Stainless Steel ASTM A564 Type 630
20010444	ACETABULAR REAMER PRECIMED® DESIGN 44mm	Stainless Steel ASTM A564 Type 630
20010445	ACETABULAR REAMER PRECIMED® DESIGN 45mm	Stainless Steel ASTM A564 Type 630
20010446	ACETABULAR REAMER PRECIMED® DESIGN 46mm	Stainless Steel ASTM A564 Type 630
20010447	ACETABULAR REAMER PRECIMED® DESIGN 47mm	Stainless Steel ASTM A564 Type 630
20010448	ACETABULAR REAMER PRECIMED® DESIGN 48mm	Stainless Steel ASTM A564 Type 630
20010449	ACETABULAR REAMER PRECIMED® DESIGN 49mm	Stainless Steel ASTM A564 Type 630
20010450	ACETABULAR REAMER PRECIMED® DESIGN 50mm	Stainless Steel ASTM A564 Type 630
20010451	ACETABULAR REAMER PRECIMED® DESIGN 51mm	Stainless Steel ASTM A564 Type 630
20010452	ACETABULAR REAMER PRECIMED® DESIGN 52mm	Stainless Steel ASTM A564 Type 630
20010453	ACETABULAR REAMER PRECIMED® DESIGN 53mm	Stainless Steel ASTM A564 Type 630
20010454	ACETABULAR REAMER PRECIMED® DESIGN 54mm	Stainless Steel ASTM A564 Type 630
20010455	ACETABULAR REAMER PRECIMED® DESIGN 55mm	Stainless Steel ASTM A564 Type 630
20010456	ACETABULAR REAMER PRECIMED® DESIGN 56mm	Stainless Steel ASTM A564 Type 630
20010457	ACETABULAR REAMER PRECIMED® DESIGN 57mm	Stainless Steel ASTM A564 Type 630
20010458	ACETABULAR REAMER PRECIMED® DESIGN 58mm	Stainless Steel ASTM A564 Type 630
20010459	ACETABULAR REAMER PRECIMED® DESIGN 59mm	Stainless Steel ASTM A564 Type 630
20010460	ACETABULAR REAMER PRECIMED® DESIGN 60mm	Stainless Steel ASTM A564 Type 630
20010461	ACETABULAR REAMER PRECIMED® DESIGN 61mm	Stainless Steel ASTM A564 Type 630
20010462	ACETABULAR REAMER PRECIMED® DESIGN 62mm	Stainless Steel ASTM A564 Type 630
20010463	ACETABULAR REAMER PRECIMED® DESIGN 63mm	Stainless Steel ASTM A564 Type 630
20010464	ACETABULAR REAMER PRECIMED® DESIGN 64mm	Stainless Steel ASTM A564 Type 630
20010465	ACETABULAR REAMER PRECIMED® DESIGN 65mm	Stainless Steel ASTM A564 Type 630
20010466	ACETABULAR REAMER PRECIMED® DESIGN 66mm	Stainless Steel ASTM A564 Type 630

20010467	ACETABULAR REAMER PRECIMED® DESIGN 67mm	Stainless Steel ASTM A564 Type 630
20010468	ACETABULAR REAMER PRECIMED® DESIGN 68mm	Stainless Steel ASTM A564 Type 630
4400DA0100	00 HALL/HUDSON ADAPTOR HALL HANDLE/HUDSON END	Stainless Steel ASTM A564 Type 630
84002001	LINEAGE® ACETABULAR BOTTOM INSERT 62-80 (1mm)	RADEL 5500
84002003	LINEAGE® ACETABULAR OUTSIDE CASE W/ LID	RADEL 5500
84002004	ACETAB TOP INSERT 40-61 (1mm) W/ HANDLE/ADAPTOR	RADEL 5500
20010440	ACETABULAR REAMER PRECIMED® DESIGN 40mm	Stainless Steel ASTM A564 Type 630
2006KIT1		
Item Number	Description	Material
Specialized		
20010400	ACETABULAR REAMER HANDLE PRECIMED® DESIGN	Stainless Steel ASTM A564 Type 630
48000040	HEMISPHERICAL REAMER SIZE 40	ASTM A276 Type 420, Grade 303 Stainless Steel
48000041	HEMISPHERICAL REAMER SIZE 41	ASTM A276 Type 420, Grade 303 Stainless Steel
48000042	HEMISPHERICAL REAMER SIZE 42	ASTM A276 Type 420, Grade 303 Stainless Steel
48000043	HEMISPHERICAL REAMER SIZE 43	ASTM A276 Type 420, Grade 303 Stainless Steel
48000044	HEMISPHERICAL REAMER SIZE 44	ASTM A276 Type 420, Grade 303 Stainless Steel
48000045	HEMISPHERICAL REAMER SIZE 45	ASTM A276 Type 420, Grade 303 Stainless Steel
48000046	HEMISPHERICAL REAMER SIZE 46	ASTM A276 Type 420, Grade 303 Stainless Steel
48000047	HEMISPHERICAL REAMER SIZE 47	ASTM A276 Type 420, Grade 303 Stainless Steel
48000048	HEMISPHERICAL REAMER SIZE 48	ASTM A276 Type 420, Grade 303 Stainless Steel
48000049	HEMISPHERICAL REAMER SIZE 49	ASTM A276 Type 420, Grade 303 Stainless Steel
48000050	HEMISPHERICAL REAMER SIZE 50	ASTM A276 Type 420, Grade 303 Stainless Steel
48000051	HEMISPHERICAL REAMER SIZE 51	ASTM A276 Type 420, Grade 303 Stainless Steel
48000052	HEMISPHERICAL REAMER SIZE 52	ASTM A276 Type 420, Grade 303 Stainless Steel
48000053	HEMISPHERICAL REAMER SIZE 53	ASTM A276 Type 420, Grade 303 Stainless Steel
48000054	HEMISPHERICAL REAMER SIZE 54	ASTM A276 Type 420, Grade 303 Stainless Steel
48000055	HEMISPHERICAL REAMER SIZE 55	ASTM A276 Type 420, Grade 303 Stainless Steel
48000056	HEMISPHERICAL REAMER SIZE 56	ASTM A276 Type 420, Grade 303 Stainless Steel
48000057	HEMISPHERICAL REAMER SIZE 57	ASTM A276 Type 420, Grade 303 Stainless Steel
48000058	HEMISPHERICAL REAMER SIZE 58	ASTM A276 Type 420, Grade 303 Stainless Steel
48000059	HEMISPHERICAL REAMER SIZE 59	ASTM A276 Type 420, Grade 303 Stainless Steel

48000060	HEMISPHERICAL REAMER SIZE 60	ASTM A276 Type 420, Grade 303 Stainless Steel
48000061	HEMISPHERICAL REAMER SIZE 61	ASTM A276 Type 420, Grade 303 Stainless Steel
48000062	HEMISPHERICAL REAMER SIZE 62	ASTM A276 Type 420, Grade 303 Stainless Steel
48000063	HEMISPHERICAL REAMER SIZE 63	ASTM A276 Type 420, Grade 303 Stainless Steel
48000064	HEMISPHERICAL REAMER SIZE 64	ASTM A276 Type 420, Grade 303 Stainless Steel
48000065	HEMISPHERICAL REAMER SIZE 65	ASTM A276 Type 420, Grade 303 Stainless Steel
48000066	HEMISPHERICAL REAMER SIZE 66	ASTM A276 Type 420, Grade 303 Stainless Steel
48000067	HEMISPHERICAL REAMER SIZE 67	ASTM A276 Type 420, Grade 303 Stainless Steel
48000068	HEMISPHERICAL REAMER SIZE 68	ASTM A276 Type 420, Grade 303 Stainless Steel
84002001	LINEAGE® ACETABULAR BOTTOM INSERT 62-80 (1mm)	RADEL 5500
84002003	LINEAGE® ACETABULAR OUTSIDE CASE W/ LID	RADEL 5500
84002004	ACETAB TOP INSERT 40-61 (1mm) W/ HANDLE/ADAPTOR	RADEL 5500

Software

The DYNASTY® Acetabular System does not use any software. Therefore, this section does not apply.

Electromagnetic Compatibility and Electrical Safety

The DYNASTY® Acetabular System does not contain electronic components. Therefore, this section does not apply.

Performance Testing – Bench

Bench testing was performed on the DYNASTY® Acetabular System to evaluate the performance characteristics of the device. The testing was conducted based on standards and FDA guidance.

The testing was performed according to "*Guidance Document for the Preparation of Premarket Notification for Ceramic Ball Hip Systems*" issued on January 10, 1995 and "*Guidance Document for Testing Non-Articulating, 'Mechanically Locked', Modular Implant Components*" issued on May 1, 1995. Testing has been summarized according to FDA's guidance document *Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications Final Guidance* issued on March 20, 1998, and contains the recommended elements. The testing is included in this submission in **Exhibit 05 (Tab Sections 027-028)**.

A. SUBJECT DYNASTY® ACETABULAR SHELLS

Testing submitted in K002149 LINEAGE® Acetabular System remains applicable to the subject DYNASTY® Acetabular Shells as the shells possess identical material, coating, lock detail, and its critical thicknesses do not create a new worst-case.

B. SUBJECT DYNASTY® A-CLASS® POLY ACETABULAR LINERS

Fatigue and dissociation testing submitted in K052026 LINEAGE® Acetabular System remains applicable to the subject DYNASTY® A-CLASS® Poly Acetabular Liners as the liners possess identical material, identical bearing surface specifications, equivalent lock detail tolerances, and its critical thicknesses do not create a new worst-case.

Additionally, wear testing submitted in K130376 (b)(4)Trade Secret [redacted] demonstrated the subject size 28mm BIOLOX® DELTA Femoral Heads to experience less average wear than the cleared worst-case size 40mm BIOLOX® DELTA Femoral Head when articulated against subject DYNASTY® A-CLASS® Poly Acetabular Liners. In that premarket filing, this testing of the subject 28mm head and liner was used to support clearance of the larger sizes 32-40mm. This testing is provided again in **Tab 028 Exhibit 05.**

C. SUBJECT BIOLOX® DELTA Femoral Heads

Testing submitted in K130376 (b)(4)Trade Secret [redacted] contained full mechanical evaluation of the subject size 28 mm heads. (b)(4)Trade Secret Process [redacted] The same testing from K130376 is provided again in this submission as **Exhibit 05 (Tab Sections 027-028)**.

This testing on the subject worst case 28mm heads was applied in K130376 to the larger diameter sizes reviewed in that filing, in burst, post-fatigue burst, and rotational stability, and pull off force. Results of all mechanical tests met the requirements according to Ceramtec procedure and the FDA Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems. Therefore the subject heads as tested have demonstrated adequate material properties.

Taper specifications are identical to those of the cleared predicate sizes, therefore no additional fretting risk is presented.

Wear testing submitted in K130376 (b)(4)Trade Secret [redacted] demonstrated the subject size 28mm BIOLOX® DELTA Femoral Heads to experience less average wear than the cleared worst-case size 40mm BIOLOX® DELTA Femoral Head when articulated against subject DYNASTY® A-CLASS® Poly Acetabular Liners.

DYNASTY® Acetabular System with Ceramic
Traditional 510(k)
Tab: Performance Testing - Bench

Test Number	Test Description	Document Location
(b)(4)Trade Secret Process	Mechanical Tests Performed on Biolox® *delta* and Biolox® *forte* 28 12/14 Heads on Ti Tapers Mechanical Tests Performed on Biolox® *delta* 28 12/14 Heads on Ti, CoCr, CoCr CCM+ and Stainless Steel WMT Tapers	**Tab 027 Exhibit 05**
	Wear Performance of Delta Ceramic Femoral Heads on Cross-Linked Polyethylene Liners	**Tab 028 Exhibit 05**

Performance Testing – Animal

Animal testing was not conducted for the DYNASTY® Acetabular System. Therefore, this section does not apply.

Performance Testing – Clinical

Clinical testing was not conducted for the DYNASTY® Acetabular System. Therefore, this section does not apply.

Part List

Part Number	Part Description
DSPCGB46	DYNASTY® Shell 46MM STD GROUP B
DSPCGB48	DYNASTY® Shell 48MM STD GROUP B
DLXPGB28	DYNASTY® A-CLASS® Crosslinked Poly Liner 28MM STD GROUP B
DLXPLB28	DYNASTY® A-CLASS® Crosslinked Poly Liner 28MM 15°GROUP B
PHA04402	BIOLOX® DELTA Femoral Head 28MM Short
PHA04404	BIOLOX® DELTA Femoral Head 28MM Medium
PHA04406	BIOLOX® DELTA Femoral Head 28MM Long

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

[redacted]

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05/11/13

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(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

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(b)(4)Trade Secret Process - Engineering Drawing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

RECEIVED
SEP 6 2000

Mr. Ehab M. Esmail
Senior Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K002149
Trade Name: Lineage" Acetabular System
Regulatory Class: II
Product Code: LPH
Dated: July 13, 2000
Received: July 17, 2000

Dear Mr. Esmail:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002149

Device Name: LINEAGE™ Acetabular System

Indications For Use:

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and,
5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002149

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 6 2005

RECEIVED
DEC 06 2005
BRENDA

Theresa Leister
Regulatory Affairs Specialist
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K052026/S1
Trade/Device Name: LINEAGE™ A-CLASS™ Poly Liner
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, JDI, LZO
Dated: October 6, 2005
Received: October 7, 2005

Dear Ms. Leister:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052026

Device Name: LINEAGE® A-CLASS™ Poly Liner

Indications For Use:
The LINEAGE® A-CLASS™ Poly Liner is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

Page 1 of 1

510(k) Number K052026

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

July 3, 2013

Wright Medical Technology, Incorporated
% Mr. Dean Nachtrab
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K130376
Trade/Device Name: DYNASTY® Acetabular System with Ceramic
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: May 29, 2013
Received: June 3, 2013

Dear Mr. Nachtrab:

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" (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 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,

Erin E. Keith

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

Enclosure

DYNASTY® Acetabular System with Ceramic
Traditional 510(k)
Tab: Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130376

Device Name: DYNASTY® Acetabular System with Ceramic

Indications for Use:

Wright Medical total hip systems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2000

DEC 1 0 2000

Mr. Ehab M. Esmail
Senior Regulatory Affairs Associate
Wright Medical Technology Incorporated
5677 Airline Road
Arlington, Tennessee 38002

Re: K003016
Trade Name: Pro-Femur R Revision Hip System
Regulatory Class: II
Product Code: LWJ
Dated: September 26, 2000
Received: September 27, 2000

Dear Mr. Esmail:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K003016

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

PROFEMUR R
REVISION HIP SYSTEM

INDICATIONS STATEMENT

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and,
5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

Prescription Use ____ (Per21 CFR 801.109) OR Over-The Counter Use ____ (Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2001

RECEIVED
OCT - 9 2001

Mr. Ehab M. Esmail
Manager, Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K012091
Trade/Device Name: PRO-FEMUR Hip System
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, LWJ, MAY
Dated: July 3, 2001
Received: July 5, 2001

Dear Mr. Esmail:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K012091

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

PRO-FEMUR
HIP SYSTEM

INDICATIONS STATEMENT

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and,
5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

Prescription Use X
(Per21 CFR 801.109)

OR

Over-The Counter Use ___
(Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices
510(k) Number K012091

WRIGHT MEDICAL TECHNOLOGY
A Wright Medical Group Company

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

RECEIVED
JUL - 8 2002

Mr. Roger D. Brown
Director, Regulatory Affairs
Wright Medical Technology
5677 Airline Road
Arlington, Tennessee 38002

Re: K021346
Trade Name: STEM Hip Replacement System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: April 26, 2002
Received: April 29, 2002

Dear Mr. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WRIGHT MEDICAL TECHNOLOGY
A Wright Medical Group Company

STEM
HIP REPLACEMENT SYSTEM

INDICATIONS STATEMENT

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1) Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) Inflammatory degenerative joint disease such as rheumatoid arthritis;
3) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed; and,
5) Treatment of fractures that are unmanageable using other techniques.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

Prescription Use X
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021346

5677 Airline Road Arlington, Tennessee 38002 901-867-9971

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2004

Mr. Ehab M. Esmail
Senior Manager, Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K031402
Trade/Device Name: Calcium Sulfate Coated Perfecta® Femoral Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: August 20, 2004
Received: August 24, 2004

Dear Mr. Esmail:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html .

Sincerely yours,

Celia M. Witten, PhD, MD
Director
Division of General, Restorative
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WRIGHT.

PERFECTA® Femoral Stem

INDICATIONS STATEMENT

510(k) Number (if known):

Device Name: PERFECTA® Femoral Stem

Indications For Use:

The PERFECTA® Femoral Stem with calcium sulfate coating is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of fractures that are unmanageable using other techniques.

The PERFECTA® Femoral Stem with calcium sulfate coating is for single use only, and is intended for use in conjunction with existing Wright Medical Technology ceramic or metal femoral heads, acetabular liners and shells, as a part of an uncemented total hip arthroplasty.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K031402

headquarters
Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002 901.867.9971 phone www.wmt.com
International subsidiaries
011.32.2.378.3995 Belgium 905.826.1600 Canada 011.33.1.45.13.24.40 France 011.49.4161.745130 Germany
011.39.0330.678.227 Italy 011.81.3.3598.0474 Japan 011.44.1483.721.404 UK

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2004

Ms. Katie Logerot
Regulatory Affairs Specialist II
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K041114
Trade/Device Name: PROFEMUR® Tapered Hip Stem
Regulation Numbers: 21 CFR 888.3320, 21 CFR 888.3330, 21 CFR 888.3350, and 21CFR 888.3353
Regulation Names: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis, Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis, Hip joint metal/polymer semi-constrained cemented prosthesis, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis and Prosthesis, hip, semi-constrained, metal/polymer, uncemented
Regulatory Class: III
Product Codes: JDL, KWA, JDI, LZO and LWJ
Dated: April 26, 2004
Received: April 28, 2004

Dear Ms. Logerot:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K041114

Indications for Use

510(k) Number (if known):

Device Name: PROFEMUR® Tapered Hip Stem

Indications For Use:
The PROFEMUR® Tapered Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson Page 1 of 1

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041114

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 9 2004

Ms. Jeanine H. Redden
Regulatory Affairs Specialist II
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K041586
Trade/Device Name: PROFEMUR® S Hip Stem
Regulation Numbers: 21 CFR 888.3320, 21 CFR 888.3330, and 21 CFR 888.3350
Regulation Names: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis; Hip joint metal/polymer semi-constrained cemented prosthesis; Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; and Prosthesis, hip, semi-constrained, metal/polymer, uncemented
Regulatory Class: III
Product Codes: JDL, KWA, JDI, LZO and LWJ
Dated: June 9, 2004
Received: June 14, 2004

Dear Ms. Redden:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: PROFEMUR® S Hip Stem

Indications For Use:
The PROFEMUR® S Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K041586

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2005 AUG 2 3 2005

Ms. Theresa Leister
Regulatory Affairs Specialist
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K051995
Trade/Device Name: PROFEMUR® RENAISSANCE™ Hip Stem
Regulation Number: 21 CFR 888.3320, 21CFR 888.3330, 21CFR 888.3350, 21 CFR 888.3353, 21CFR 888.3358
Regulation Name: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis, Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis, Hip joint metal/polymer semi-constrained cemented prosthesis, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: III
Product Code: JDL, KWA, JDI, LZO, LPH
Dated: July 22, 2005
Received: July 25, 2005

Dear Ms. Leister:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

Page-2- Ms. Theresa Leister

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: PROFEMUR® RENAISSANCE™ Hip Stem

Indications For Use:
The PROFEMUR® RENAISSANCE™ Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K051995

1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2006

JAN 30 2006

Ms. Theresa Leister
Regulatory Affairs Specialist
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K052915
Trade/Device Name: Profemur XTR Cemented Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis
Regulatory Class: III
Product Codes: KWA, JDL, LZO, JDI
Dated: January 16, 2006
Received: January 18, 2006

Dear Ms. Leister:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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

Page 2 – Ms. Theresa Leister

CFR Part 807); labeling (21 CFR Part 801); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

PROFEMUR® XTR Cemented Hip Stem
INDICATIONS STATEMENT

510(k) Number (if known): K052915

Device Name: PROFEMUR® XTR Cemented Hip Stem

Indications For Use:

The PROFEMUR® XTR Cemented Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052915

DEPARTMENT OF HEALTH & HUMAN SERVICES JAN 17 2006 Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2006

Theresa Leister
Regulatory Affairs Specialist II
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K053588
Trade/Device Name: PROFEMUR® LX Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis
Regulatory Class: III
Product Code: KWA, LZO, JDI.
Dated: December 22, 2005
Received: December 23, 2005

Dear Ms. Leister:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such 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 devices comply 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson,
Acting Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 Division
D.O.
f/t:ELF:rrr: 1/12/06

K053588

Indications for Use

510(k) Number (if known):

Device Name: PROFEMUR® LX Hip Stem

Indications For Use:
The PROFEMUR® LX Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K053588

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2006

MAY 15 2006

Mr. Matt Paul
Regulatory Affairs Specialist
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K060358
Trade/Device Name: PROFEMUR® TL Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL, LWJ, JDI, LZO
Dated: April 10, 2006
Received: April 12, 2006

Dear Mr. Paul:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K060358

Indications for Use

510(k) Number (if known):

Device Name: PROFEMUR® TL Hip Stem

Indications For Use:
The PROFEMUR® TL Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K060358

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2008

Wright Medical Technology, Inc.
% Mr. Ryan Ross
5677 Airline Road
Arlington, TN 38002

Re: K080663
Trade/Device Name: Profemur LX Revision ⅝ Coated Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, LZO, MBL
Dated: January 24, 2008
Received: March 10, 2008

Dear Mr. Ross:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K080663 (pg 1/1)

Indications for Use

510(k) Number (if known):

Device Name: PROFEMUR® LX Revision 5/8 Coated Hip Stem

Indications For Use:
The PROFEMUR® LX Revision 5/8 Coated Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

The PROFEMUR® LX Revision 5/8 Coated Hip Stem is intended to be used in cementless total hip arthroplasty.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for M.K.

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Page 1 of 1

510(k) Number K080663

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2008

Wright Medical Technology, Inc.
% Mr. Ryan Ross
Regulatory Affairs Specialist
5677 Airline Road
Arlington, TN 38002

Re: K081090
Trade/Device Name: PROFEMUR® LX 5/8 Coated Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, LZO, MBL
Dated: April 14, 2008
Received: April 18, 2008

Dear Mr. Ross:

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.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081090 (pg 1/1)

Device Name: PROFEMUR® LX 5/8 Coated Hip Stem

Indications For Use:
The PROFEMUR® LX 5/8 Coated Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

The PROFEMUR® LX 5/8 Coated Hip Stem is intended to be used in cementless total hip arthroplasty.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

Page 1 of 1

510(k) Number K081090

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Wright Medical Technology, Inc.
% Mr. Ryan Ross
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

AUG 25 2009

Re: K091423
Trade/Device Name: Profemur Hip System Modular Necks
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA, JDL, LWJ, LPH, MBL, LZO
Dated: August 17, 2009
Received: August 18, 2009

Dear Mr. Ross:

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.

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 go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K091423

Device Name: PROFEMUR® Hip System Modular Necks

Indications For Use:
The PROFEMUR® Hip System Modular Necks are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

Modular necks can be used during either cemented or uncemented femoral and acetabular arthroplasty.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MNM
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091423 Page 1 of 1

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Wright Medical Technology Inc.
% Mr. Matt Paul
Manager, Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

MAY 10 2011

Re: K110399
Trade/Device Name: GLADIATOR® Plasma Classic Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL, LZO
Dated: February 9, 2011
Received: February 11, 2011

Dear Mr. Paul:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

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

Enclosure

K110399

WRIGHT TRADITIONAL 510(k) PREMARKET NOTIFICATION
GLADIATOR® Plasma Classic Hip Stem

WRIGHT.

Indications for Use

510(k) Number (if known):

Device Name: **GLADIATOR® Plasma Classic Hip Stem**

The GLADIATOR® Plasma Classic Hip Stem is intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

GLADIATOR® Plasma Classic Hip Stems are intended for use during uncemented hip arthroplasty.

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)

for M. Melkerson
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

K110399
510(k) Number February 9, 2011 Page 1 of 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Wright Medical Technology, Inc.
% Mr. Gregory Neal
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

AUG 19 2011

Re: K111698
Trade/Device Name: PROFEMUR® E Cementless Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL, LPH, LZO
Dated: July 21, 2011
Received: July 22, 2011

Dear Mr. Neal:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

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

Enclosure

K111698 (pg 1/1)

WRIGHT.

Indications for Use

Device Name: PROFEMUR® E Cementless Hip Stem

Indications For Use:

The PROFEMUR® E Cementless Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

The PROFEMUR® E Cementless Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of an uncemented total hip arthroplasty.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M Melkerson
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Page 1 of 1

510(k) Number K111698

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Wright Medical Technology, Inc.
% Mr. Gregory Neal
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

AUG 19 2011

Re: K111699
Trade/Device Name: PROFEMUR® Z Titanium Plasma Sprayed Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL, LPH, LZO
Dated: July 21, 2011
Received: July 22, 2011

Dear Mr. Neal:

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.

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Page - 2 – Mr. Gregory Neal
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.

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Sincerely yours,

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

Enclosure

K111677 (pg 1/1)

WRIGHT.

Indications for Use

Device Name: PROFEMUR® Z Titanium Plasma Sprayed Hip Stem

Indications For Use:

The PROFEMUR® Z Titanium Plasma Sprayed Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

The PROFEMUR® Z Titanium Plasma Sprayed Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of an uncemented total hip arthroplasty.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111699

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 14 2011

Wright Medical Technology, Inc.
% Matt Paul
5677 Airline Rd
Arlington, TN 38002

Re: K111910
Trade/Device Name: Gladiator Hip Stems
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL, LPH, LZO, JDI
Dated: October 12, 2011
Received: October 13, 2011

Dear Mr. Paul:

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.

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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

Page - 2 – Mr. Matt Paul

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.

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Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K111910(pg 1/1)

Device Name: Gladiator Hip Stems

Indications For Use:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The Gladiator cpTi Plasma Sprayed hip stem is intended for cementless hip arthroplasty.

The Gladiator Cemented hip stem is intended for cemented hip arthroplasty.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111910

K112080

DEC 28 2011

510(k) Summary of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the PROFEMUR® Preserve Hip Stems.

Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd, Arlington TN, 38002 (800) 238-7188
Date:	July 14, 2011
Contact Person:	Matt Paul *Project Regulatory Affairs Specialist*
Proprietary Name:	Preserve Hip Stems
Common Name:	Hip Stem
Classification Name and Reference:	21 CFR 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis Class III
Subject Product Code and Panel Code:	Orthopedics/87/KWA, JDL, LZO
Predicate Devices Name and Number:	PROFEMUR® Hip System Modular Necks PROFEMUR® TL Hip Stem PROFEMUR® Z (STEM) PRO-FEMUR® Hip System 510(k): K100866, K091423, K060358, K021346, K012091
Predicate Classification and Number:	Orthopedics/87/ KWA, 888.3330

Device Information

A. Device Description

The Preserve stems are short modular hip stems that couple with modular necks. Design features of the stems are summarized below:

- Cementless stem with proximal cpTi plasma spray coating
  - Available in 9 sizes (4-12)
  - Manufactured from Ti alloy

The Preserve Hip Stems were evaluated via mechanical testing; including fatigue, fretting, and distraction evaluation. A review of these results indicates that the Preserve Hip Stems are equivalent to predicate devices and are capable of withstanding expected *in vivo* loading without failure.

K112080

B. Intended Use

The Preserve Hip Stems are intended for use in uncemented total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

C. Technological Characteristic of the Device

The Preserve Hip Stem has the same technological characteristics as the predicate devices. Preserve Hip Stems are straight uncemented hip stems with a modular design. They feature both a triple tapered design and a proximal medial curvature. The proximal portion is coated with a commercially pure titanium plasma spray (conforming to ASTM F1580) that decreases distally in thickness. The materials used for the Preserve® Hip Stems are identical to the materials used for the predicate devices.

D. Nonclinical Testing

The Preserve Hip Stems have been tested in distal and proximal fatigue evaluation per the loading regimen prescribed by ISO 7206-4, -6 and -8.

E. Clinical Testing

Clinical data was not provided for the class III hip stem.

F. Conclusions

The indications for use of the Preserve Hip Stems are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the Preserve Hip Stem is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Wright Medical Technology, Inc.
% Mr. Matt Paul
5677 Airline Rd
Arlington TN, 38002

DEC 28 2011

Re: K112080
Trade/Device Name: Preserve Hip Stems
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL, LZO
Dated: December 22, 2011
Received: December 23, 2011

Dear Mr. Matt Paul:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

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

Enclosure

K112080

Indications for Use

510(k) Number (if known):

Device Name: PRESERVE Hip Stems

Indications For Use:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The Preserve hip stem is intended for cementless hip arthroplasty.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112080

Page 1 of 1

K112150 NOV 23 2011

510(k) Summary of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the PROFEMUR® GLADIATOR® HA Hip Stems.

Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd, Arlington TN, 38002 (800) 238-7188
Date:	July 22, 2011
Contact Person:	Matt Paul *Project Regulatory Affairs Specialist*
Proprietary Name:	PROFEMUR® GLADIATOR® HA Hip Stem
Common Name:	Hip Stem
Classification Name and Reference:	21 CFR 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis Class III
Subject Product Code and Panel Code:	Orthopedics/87/KWA, JDL, LZO
Predicate Devices Name and Number:	PROFEMUR® Hip System Modular Necks PROFEMUR® Z PROFEMUR® Hip System PROFEMUR® TL Hip Stem PROFEMUR® Renaissance HA CORAIL® Hip Prosthesis 510(k): K100866, K091423, K021346, K012091, K060358, K051995, K953111, K042992
Predicate Classification and Number:	Orthopedics/87/ KWA, 888.3330

Device Information

A. Device Description

The PROFEMUR® GLADIATOR® HA stems are hydroxyapatite coated hip stems that couple with modular necks. Design features of the stems are summarized below:

- Cementless stem with hydroxyapatite plasma spray coating
- Available in 10 sizes
- Manufactured from Ti alloy (Ti-6Al-4V) conforming to ASTM F620
- Hydroxyapatite coating conforming to ASTM F1185
- Available with and without collar

K112150

The PROFEMUR® GLADIATOR® HA Hip Stems were evaluated via mechanical testing; including fatigue, fretting, and distraction evaluation. A review of these results indicates that the GLADIATOR® HA Hip Stems are equivalent to predicate devices and are capable of withstanding expected *in vivo* loading without failure.

B. Intended Use

The PROFEMUR® GLADIATOR® HA Hip Stems are intended for use in uncemented total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

The PROFEMUR® GLADIATOR® HA hip stem is intended for cementless hip arthroplasty.

C. Technological Characteristic of the Device

The PROFEMUR® GLADIATOR® HA Hip Stems have the same technological characteristics as the predicate device. PROFEMUR® GLADIATOR® HA Hip Stems are straight uncemented hip stems with a modular design. They feature a proximal trapezoidal cross-section and a distal rectangular cross-section. For fixation stability in three planes, the stem has a vertically tapered profile in the frontal and lateral planes. The materials used for the PROFEMUR® GLADIATOR® HA Hip Stems are identical to the materials used for the predicate devices.

D. Nonclinical Testing

The PROFEMUR® GLADIATOR® HA Hip Stems have been tested in distal and proximal fatigue evaluation per the loading regimen prescribed by ISO 7206-4, -6 and -8.

E. Clinical Testing

Clinical data was not provided for the class III hip stem.

F. Conclusions

The indications for use of the PROFEMUR® GLADIATOR® HA Hip Stems are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the PROFEMUR® GLADIATOR® HA Hip Stems are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

NOV 23 2011

Wright Medical Technology, Inc.
% Mr. Matt Paul
5677 Airline Rd.
Arlington, TN 38002 US

Re: K112150
Trade/Device Name: Profemur Gladiator HA Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.
Regulatory Class: Class III
Product Code: KWA, JDL, LZO
Dated: November 18, 2011
Received: November 21, 2011

Dear Mr. Matt Paul:

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.

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Sincerely yours,

Erin L Keith
for Mark N. Melkerson
Director
Division of Surgical, Orthopedic & Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112150

Device Name: PROFEMUR® Gladiator HA Hip Stems

Indications For Use:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® Gladiator HA Hip Stem is intended for cementless hip arthroplasty.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael Chaves for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112150

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Wright Medical Technology, Inc.
% Mr. Yuan Li
5677 Airline Rd.
Arlington, TN 38002 US

AUG 9 2012

Re: K121221
Trade/Device Name: Profemur Z Revision Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Cemented or Non-Porous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI
Dated: July 9, 2012
Received: July 10, 2012

Dear Mr. Li:

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

Page 2 – Mr. Yuan Li

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

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

Enclosure

K121221

Indications for Use

510(k) Number (if known):

Device Name: PROFEMUR® Z Revision Hip Stem

Indications For Use:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® Z Revision Hip Stem is intended for cementless hip arthroplasty.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121221

Page 1 of 1

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

Wright Medical Technology, Incorporated
% Yuan Li
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Letter dated: February 8, 2013

Re: K123688
Trade/Device Name: PROFEMUR® TL Classic Stems
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, JDI
Dated: November 26, 2012
Received: December 3, 2012

Dear Yuan Li:

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

Page 2 – Yuan Li

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

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

Enclosure

WRIGHT.

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123688 (pg 1/1)

Device Name: PROFEMUR® TL Classic Stems

Indications for Use:

The PROFEMUR® TL Classic Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® TL Classic Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens

Division of Orthopedic Devices

Headquarters
Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002 901.867.5971 phone
www.wmt.com

(b)(4)Trade Secret Process - Testing Report

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Appendix 10.4
Literature References

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Appendix 10.5
Statistical Analysis

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RADIATION STERILIZATION PROCESS

Source/Type of Radiation: Cobalt 60/Gamma radiation

Sterility Assurance Level: 10^{-6}

Validation Method: VD_{max}^{25}

Dosage: (b) (4) [redacted]

Validation: Validation is accomplished by following the procedures set forth by the Association for the Advancement of Medical Instrumentation (AAMI/ISO) Sterilization of Health Care Products-Requirements for Validation and Routine Control-Radiation Sterilization, ANSI/AAMI/ISO 11137:2006 (VD_{max}^{25}).

Description of Packaging: The packaging consists of either a PETG thermoformed tray with Tyvek lid heat sealed to the tray and placed inside a second PETG tray with Tyvek lid or a poly Tyvek pouch sealed and placed inside a second poly Tyvek pouch. The trays or pouches are inserted into a paperboard carton that is shrink wrapped.

Pyrogen Statement: These products are not labeled as "non-pyrogenic." Applications of orthopedic implants are such that routine pyrogen testing is not required.

Primary Contract Sterilizer: (b) (4) [redacted]

FDA Registration No.:

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ETHYLENE OXIDE (EtO) STERILIZATION PROCESS

Source/Type of Sterilization: 100% Ethylene Oxide

Sterility Assurance Level: 10^{-6}

Type of Cycle: Overkill

Dosage: N/A

Validation: Validation is accomplished by following the procedures set forth by Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization, No. ANSI/AAMI/ISO 11135.

EtO Residuals: As part of our validation of Ethylene Oxide (EO) Sterilization, the devices will not retain EO residual levels greater than the proposed maximum residue limits and maximum levels of exposure as specified in ANSI/AAMI/ISO 10993-7.

Worst-case device was selected based on product, density, size, and worst case for EtO sterilization.
Selected devices: LINEAGE® Acetabular Poly Liner (K002149), LINEAGE® Ceramic Head (K893685)

Product	Surface area of representative product (cm^2)	Total EO Residual after 3X Exposure, measured on Day 1 (mg/day)	EO Tolerable Contact Limits, measured on Day 1 (mg/day)	Total ECH Residual after 3X Exposure, measured on Day 1 (mg/day)	ECH Tolerable Contact Limits, measured on Day 1 (mg/day)
(b) (4) [redacted]					

ND = Not Detected at detection limit; ECH = Ethylene Chlorohydrin
* Calculation performed using Toxikon's EO Instrument Detection Limit of 1µg/mL
¥ Calculation performed using Toxikon's ECH Instrument Detection Limit of 2.5 µg/mL

Description of Packaging: The packaging consists of either a PETG thermoformed tray with Tyvek lid heat sealed to the tray and placed inside a second PETG tray with Tyvek lid or a poly Tyvek pouch sealed and placed inside a second poly Tyvek pouch. The trays or pouches are inserted into a paperboard carton that is shrink wrapped.

Pyrogen Statement: These products are not labeled as "non-pyrogenic." Applications of orthopedic implants are such that routine pyrogen testing is not required.

(b) (4) [redacted]

Primary Contract Sterilizer:

FDA Registration No.:

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

LABEL P/N 134762

WRIGHT **Wright Medical Technology, Inc.**
5677 Airline Road | Arlington, TN 38002

EC REP **Wright Medical EMEA**
Krijgsman 11 1186 DM Amstelveen, The Netherlands

CONTENTS: 1 EACH
DYNASTY® PC SHELL

Hip Acetabular Shell
Coque acétabulaire pour hanche
Acetabulumschale, Hüfte
Copa acetabular para cadera
Guscio acetabolare
Heup acetabulumschil
Componente acetabular em concha
Kalça Asetabüler Kabuğu
髋臼杯

CE 0086

② ℞ ONLY ⚠

IMPLANT MATERIAL: Ti6Al4V

REF **DSPC-GB46** LOT **ABC124**

SIZE	GROUP	PROFILE	SURFACE	STYLE	FLARE
46mm	B	STD	POROUS	QUAD	NO

DYNASTY® PC SHELL

+H427DSPCGB461P

+$$0118ABC124FC

STERILE R

2010-01
2016-01

FPO091124

WRIGHT

COLOR CODE BRONZE

WRIGHT **Wright Medical Technology, Inc.**
5677 Airline Road | Arlington, TN 38002

REF **DSPC-GB46** LOT **ABC124**
DYNASTY® PC SHELL
SIZE: 46mm GROUP: B

+H427DSPCGB461P

+$$0118ABC124FC

2010-01
2016-01

STERILE R

COLOR CODE BRONZE

WRIGHT **Wright Medical Technology, Inc.**
5677 Airline Road | Arlington, TN 38002

REF **DSPC-GB46** LOT **ABC124**

SIZE	GROUP	PROFILE	SURFACE	STYLE	FLARE
46mm	B	STD	POROUS	QUAD	NO

DYNASTY® PC SHELL
IMPLANT MATERIAL: Ti6Al4V

2010-01 2016-01 ② ℞ ONLY **STERILE R** CE 0086

COLOR CODE BRONZE

WRIGHT **Wright Medical Technology, Inc.**
5677 Airline Road | Arlington, TN 38002

REF **DSPC-GB46** CE 0086
LOT **0123456789**
DYNASTY® PC SHELL
SIZE: 46mm GROUP: B
IMPLANT MATERIAL: Ti6Al4V
2010-01 2016-01 **STERILE R**
ATTACH TO PATIENT RECORD
COLOR CODE BRONZE

WRIGHT **Wright Medical Technology, Inc.**
5677 Airline Road | Arlington, TN 38002

REF **DSPC-GB46** CE 0086
LOT **0123456789**
DYNASTY® PC SHELL
SIZE: 46mm GROUP: B
IMPLANT MATERIAL: Ti6Al4V
2010-01 2016-01 **STERILE R**
ATTACH TO PATIENT RECORD
COLOR CODE BRONZE

WRIGHT **Wright Medical Technology, Inc.**
5677 Airline Road | Arlington, TN 38002

REF **DSPC-GB46** CE 0086
LOT **0123456789**
DYNASTY® PC SHELL
SIZE: 46mm GROUP: B
IMPLANT MATERIAL: Ti6Al4V
2010-01 2016-01 **STERILE R**
ATTACH TO PATIENT RECORD
COLOR CODE BRONZE

WRIGHT **Wright Medical Technology, Inc.**
5677 Airline Road | Arlington, TN 38002

REF **DSPC-GB46** CE 0086
LOT **0123456789**
DYNASTY® PC SHELL
SIZE: 46mm GROUP: B
IMPLANT MATERIAL: Ti6Al4V
2010-01 2016-01 **STERILE R**
ATTACH TO PATIENT RECORD
COLOR CODE BRONZE

WRIGHT **Wright Medical Technology, Inc.**
5677 Airline Road | Arlington, TN 38002

REF **DSPC-GB46** CE 0086
LOT **0123456789**
DYNASTY® PC SHELL
SIZE: 46mm GROUP: B
IMPLANT MATERIAL: Ti6Al4V
2010-01 2016-01 **STERILE R**
ATTACH TO PATIENT RECORD
COLOR CODE BRONZE

WRIGHT **Wright Medical Technology, Inc.**
5677 Airline Road | Arlington, TN 38002

REF **DSPC-GB46** CE 0086
LOT **0123456789**
DYNASTY® PC SHELL
SIZE: 46mm GROUP: B
IMPLANT MATERIAL: Ti6Al4V
2010-0 **STERILE R**
ATTACH TO PATIENT RECORD
COLOR CODE BRONZE

LABEL P/N 134782

WRIGHT.
Arlington, TN 38002 USA

EC REP Wright Medical EMEA
Krijgsman 11 1186 DM Amstelveen, The Netherlands

CONTENTS: 1 EACH

DYNASTY® A-CLASS® POLY LINER

CE 0086

Hip Acetabular Liner
Revêtement intérieur acétabulaire pour hanche
Acetabulumeinsatz, Hüfte
Revestimiento acetabular para cadera
Inserto acetabolare
Heup acetabulumvoering
Revestimento acetabular para anca
Kalça Asetabüler Lineri
髖臼內衬

STERILE EO

IMPLANT MATERIAL: UHMWPE

② Rx ONLY ⚠ i

REF **DLXP-GB28** LOT **ABC124**

GROUP	I.D. SIZE	LIP	LINER
B	28mm	0°	STD

DYNASTY® A-CLASS® POLY LINER

+H427DLXPGB281T

+$$10 12ABC124TK

2009-10
2012-10

FPO091119

WRIGHT.

COLOR CODE BRONZE

REF **DLXP-GB28** LOT **ABC124**

DYNASTY® A-CLASS® POLY LINER

+H427DLXPGB281T

+$$10 12ABC124TK

2009-10
2012-10

COLOR CODE BRONZE

REF **DLXP-GB28** LOT **ABC124**

CE 0086

② Rx ONLY

GROUP	I.D. SIZE	LIP	LINER
B	28mm	0°	STD

2009-10
2012-10

DYNASTY® A-CLASS® POLY LINER
IMPLANT MATERIAL: UHMWPE

STERILE EO

COLOR CODE BRONZE

WRIGHT. Wright Medical Technology, Inc.
5677 Airline Road | Arlington, TN 38002

REF **DLXP-GB28**
LOT **ABC124**

CE 0086

DYNASTY® A-CLASS® POLY LINER
I.D. SIZE: 28mm GROUP: B
IMPLANT MATERIAL: UHMWPE

2009-10 2012-10

STERILE EO

ATTACH TO PATIENT RECORD

COLOR CODE BRONZE

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5677 Airline Road | Arlington, TN 38002

REF **DLXP-GB28**
LOT **ABC124**

CE 0086

DYNASTY® A-CLASS® POLY LINER
I.D. SIZE: 28mm GROUP: B
IMPLANT MATERIAL: UHMWPE

2009-10 2012-10

STERILE EO

ATTACH TO PATIENT RECORD

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DYNASTY® A-CLASS® POLY LINER
I.D. SIZE: 28mm GROUP: B
IMPLANT MATERIAL: UHMWPE

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2009-10 2012-10

STERILE EO

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COLOR CODE BRONZE

LABEL P/N 134799

Arlington, TN 38002 USA

EC REP **Wright Medical EMEA**
Hoogoorddreef 5 1101 BA Amsterdam, NLD

CONTENTS: 1 EACH

BIOLOX® DELTA FEMORAL HEAD

Hip Femoral Head
Tête fémorale (hanche)
Femurkopf, Hüfte
Cabeza femoral para cadera
Testa femorale per anca
Heup femurkop
Cabeça femoral
Kalça Femur Başı
髋关节股骨头

IMPLANT MATERIAL: ALUMINA MATRIX COMPOSITE

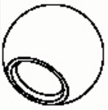
℞ ONLY STERILE R CE 0086

BIOLOX® is a registered trademark of CeramTec AG

REF **PHA04402** LOT ABC124

BIOLOX® DELTA FEMORAL HEAD

SIZE	NECK LENGTH	TAPER
28mm	SHORT	SLT – 12/14 5°43'30"



FPOA0120524 2010-01 2018-01

REF **PHA04402** LOT **ABC124**

BIOLOX® DELTA FEMORAL HEAD

+H427PHA04402 15

+$$0118ABC12452

2010-01
2018-01

REF PHA04402 LOT ABC124

SIZE	NECK LENGTH	TAPER
28mm	SHORT	SLT – 12/14 5°43'30"

℞ ONLY CE 0086

2010-01
2018-01

BIOLOX® DELTA FEMORAL HEAD

STERILE R

IMPLANT MATERIAL: ALUMINA MATRIX COMPOSITE

Wright Medical Technology, Inc.
5677 Airline Road | Arlington, TN 38002

REF PHA04402
LOT ABC124
BIOLOX® DELTA FEMORAL HEAD
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TAPER: SLT – 12/14 5°43'30"
IMPLANT MATERIAL: ALUMINA MATRIX COMPOSITE
CE 0086 2010-01 2018-01 STERILE R
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5677 Airline Road | Arlington, TN 38002

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CE 0086 2010-01 2018-01 STERILE R
ATTACH TO PATIENT RECORD

Symbol	Definition 146302 Rev 0
LOT	BATCH CODE
REF	CATALOG NUMBER
	DO NOT RE-USE
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	CONSULT OPERATING INSTRUCTIONS
	USE BY DATE
	TEMPERATURE LIMITATION
	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
	DATE OF MANUFACTURE
	MANUFACTURER

EC REP	AUTHORIZED EC REPRESENTATIVE IN THE EUROPEAN COMMUNITY
STERILE EO	STERILIZED USING ETHYLENE OXIDE
STERILE R	STERILIZED USING RADIATION
STERILE A	STERILIZED USING ASEPTIC PROCESSING TECHNIQUES
STERILE GAS	STERILIZED USING GAS PLASMA
Rx ONLY	CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
	DO NOT USE IF PACKAGING IS DAMAGED
NON STERILE	NON STERILE
	DO NOT RESTERILIZE
STERILE	STERILE

DYNASTY®

Acetabular System

SURGICAL TECHNIQUE

Create Motion.® WRIGHT.

Indications

Intended Use

Wright Medical total hip systems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed

Rough grit blast surfaces and the hydroxyapatite, titanium plasma spray, and calcium sulfate coatings applied to implant surfaces are intended for uncemented arthroplasty. Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty. Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.

Contraindications

Patients should be warned of these contraindications.

Contraindications include:

1) overt infection;
2) distant foci of infections (which may cause hematogenous spread to the implant site);
3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
4) skeletally immature patients (patient is less than 21 years of age at the time of surgery);
5) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
6) neuropathic joints;
7) hepatitis or HIV infection;
8) neurological or musculoskeletal disease that may adversely affect gait or weightbearing.

Cobalt Chrome Modular Necks are not for use with the following devices:

- Alumina Ceramic Femoral Heads (size 28mm Long)
- PROFEMUR® E Size 0 hip stem (not available in the U.S.)

Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. The patient should not have unrealistic functional expectations for occupations or activities that include substantial walking, running, lifting, or muscle strain.

Device-Specific Warnings and Precautions

NEVER combine modular or bearing components made by different manufacturers.

In the U.S., the "DYNASTY® A-CLASS® Poly (UHMWPE) Liners" are designed to articulate with the following ceramic femoral heads:

- Alumina "Ceramic Femoral Head" (Biolox Forte diameters 28-36mm)
- Alumina "CONSERVE® Total BCH® Femoral Head" (diameter range 38-54mm)
- "Alumina Matrix Composite" (Biolox Delta) ceramic heads (diameter range 28-40mm)

Additionally in the U.S., the Alumina (Biolox Forte) "Ceramic Femoral Heads" are designed to articulate with "LINEAGE® DURAMER®" and "LINEAGE® A-CLASS®" UHMWPE polyethylene acetabular liners (diameters 28-36mm).

Acetabular Fixation Screws
Perforation of the pelvis with dome fixation screws or rim screws is to be completely avoided. Care is to be used when determining and selecting the proper length of screws to be used to prevent perforation of the pelvis.

Modular Acetabular Shell/Liner

- Fixation screws, when used, should be fully seated to ensure stable fixation of the shell, and avoid interference with the liner component. Before implanting, be certain the selected shell and liner are compatible. Prior to seating the liner component into the shell component, surgical debris must be cleaned from the interior of the shell and the shell must be thoroughly dried. Debris and fluid may inhibit the liner from locking into the shell component. Failure to properly seat the liner into the shell can lead to disassociation of the liner from the shell.
- **Note:** There is currently no clinical evidence supporting the long term use of large diameter femoral heads with cross-linked polyethylene liners.

In order to prevent mismatch of tapers:

- Modular liners from Wright Medical Technology, Inc (Wright) must be used only with shell components of the same system from Wright.
- An exception to this rule is that all Wright 18° taper liner components can be used with 18° modular acetabular shells.

Cross-linked "DYNASTY® A-CLASS® Poly Liners" are to be used with ceramic heads or the following metal heads.
The **Wright 18˚ taper metal liners** are to be used only with the following superfinished Wright metal heads:

- "LINEAGE®/TRANSCEND® Femoral Head" SuperFinished CoCr with the SLT taper
- "CONSERVE® BFH® Head" with the SLT taper
- "CONSERVE® A-CLASS® BFH® Head" with the SLT taper
- "CONSERVE® Total A-CLASS® Femoral Head" with the SLT taper

Ceramic femoral heads should not be placed on scratched or previously assembled metal tapers as this may lead to a ceramic fracture.

Fracture of ceramic components is a serious complication. Special care must be taken with ceramic devices, which must not be used if dropped, even in the absence of any apparent damage. Only use a plastic tip to introduce the ceramic devices. Patients should be advised to report unusual noise and/or sharp pain as both can be an indication of fracture. Decision to revise should not be postponed as ceramic fragments can cause severe damage to surrounding soft tissue and metal components. Revision outcomes after ceramic fractures can be compromised by the remaining ceramic debris present in the tissue even after careful debridement. Damage has been reported in polyethylene and metal components used in revisions after ceramic fractures. Surgeons are advised to carefully consider all available implant options on an individual basis. It must be noted that removal of all components including femoral stems and acetabular shells may not prevent accelerated wear due to ceramic debris in the tissue. Partial or complete synovectomy has been recommended by some authors.

The size 28mm Long Neck **alumina (Biolox Forte) "Ceramic Femoral Heads"** are indicated for use only with titanium alloy femoral stems. All other sizes of the **alumina (Biolox Forte) "Ceramic Femoral Heads"** and all sizes of the Alumina Matrix Composite Heads ("Biolox Delta Femoral Head") are indicated for use with titanium alloy, cobalt chrome, or Wright stainless steel (not available in the U.S. or Canada) femoral stems.

Please consult Instructions For Use package insert for additional risk information.

Preoperative Planning

Preoperative assessment of the appropriate size and position of the acetabular component will provide intraoperative guidance for acetabular reaming.

An A/P X-ray of the pelvis will aid in leg length and offset assessment. Accurate preoperative templating requires good quality standardized radiographs of the pelvis and operative hip. Leg length discrepancies should be determined preoperatively and addressed intraoperatively.

Radiographic overlays for the DYNASTY® Acetabular Cup System are available in 15 percent magnification.

CAUTION: Preoperative templating is intended for estimation purposes only. Final component size and position should be determined intraoperatively.

Surgical Technique

Preparation of the Acetabulum

For primary cases, ream the acetabulum sequentially, starting with the smallest reamer that conforms to the acetabular cavity. Gradually enlarge the acetabulum by reaming articular cartilage until a continuous surface of cancellous bone is exposed. For revision cases, ream the acetabulum sequentially, starting with the smallest reamer that conforms to the acetabular cavity. Gradually enlarge the acetabulum by reaming until a continuous surface of cancellous bone is exposed.

Sizing the Acetabulum

Thread the trial shell onto the impactor handle to check the size of the acetabulum. The trial shells are a complete hemisphere and are undersized by 1mm compared to the actual implant. The trials also have three large open windows for visualization.

Inserting the Shell

Thread the appropriate size shell onto the impactor. Laser markings on the rim of the shell corresponding to the location of the screw holes should be positioned between the plane of the anterior superior iliac spine and the anterior inferior iliac spine. Impact the cup into the acetabulum making sure the screw holes are in the appropriate location. Complete seating of the implant can be confirmed through the apical hole and screw holes.

***CAUTION:* Caution should be taken to avoid scratching or denting the rim or internal taper of the shell. Injury to the shell taper will create stress-risers at the shell-liner interface. If the locking mechanism is damaged during implantation, the shell should be replaced.**

Screw Placement

Determine the screw location and select a suitable length drill bit. Drill bits are provided in 3.2 and 4.5mm diameters, in modular and non-modular options. The drill guide is also available in 3.2 and 4.5mm diameters.

Position the drill guide into the shell ensuring that it is placed into one of the screw holes. Insert the drill into the guide and carefully drill through the acetabular cortex. Use the screw depth gauge to determine the appropriate length screw.

If extremely hard bone is encountered, a series of bone taps are provided to aid in screw insertion. Grasp the screw head with the screw-holding forceps and utilize the hex screwdriver to orient and fixate the screw. Release the screw-holding forceps to allow for the countersinking of the screw head.

Ensure the screw head is completely seated and does not protrude into the shell space, as this may prevent the liner from seating.

CAUTION: Due to intrapelvic vascularity, screw placement in the medial aspect of the acetabulum must be carefully considered.

CAUTION: To ensure proper prosthetic liner seating in the shell, all screw heads must be seated below the inner surface of the shell. Full and unobstructed seating is crucial to implant fit and longevity.

Trial Reduction

Once the shell is securely fit into the acetabulum and the femoral stem is implanted, proceed to determining the final component size. The head trials range in size from 28-40mm in diameter. Once a trial head and trial liner are selected and put in place, a trial reduction may be performed.

Apical Hole Plug Insertion

Do not insert the apical hole plug until after final trial reduction with the trial liners. After the trial reduction, seal the apical hole with the apical hole plug. The poly rod will break off at the plug once it is tightened into the apical hole. A final tightening of the hole plug should be performed using a 3.5mm hex screwdriver.

Liner Placement

Clean out any soft tissue from the inner taper area before impacting and engaging the implant and the liner. Insert the liner by hand, ensuring that the face of the liner is parallel with the face of the shell. Ensure the liner is flush with the shell.

To engage the implant liner, assemble the modular trial head impactor to the impactor handle. Tighten the trial head impactor in a clockwise direction until it can no longer be turned. Attach the appropriate femoral head trial corresponding to the liner I.D. Place head trial into the liner and apply a series of firm mallet blows to fully seat and engage the liner.

Femoral Head Implantation

The neck taper and head taper must be clean and dry. Attach the ceramic head to the neck by twisting the head onto the neck while applying pressure. Place the plastic head impactor onto the head and lightly tap the head impactor in an axial direction. NEVER impact the ceramic head with a metal object.

Prosthetic Extraction

To remove a poly liner, utilize the flexible drill bit with an acetabular drill guide and drill a hole slightly off-center from the liner apex. Using a 3.5mm hex screwdriver, thread a 20mm cancellous screw into the drilled hole.

Ordering Information

DYNASTY® Acetabular Cup System

DYNASTY® 10 Hole Revision Shells (cleared under K122382)	
DBFRGB46	DYNASTY® BF 10-Hole.Revision.Shell 46mm Group B
DBFRGB48	DYNASTY® BF 10-Hole.Revision.Shell 48mm Group B
DYNASTY® BIOFOAM® 3-Hole Quadrant Shells (cleared under K122382)	
DBFPGB46	DYNASTY® BIOFOAM® 3-hole shell 46mm Group B
DBFPGB48	DYNASTY® BIOFOAM® 3-hole shell 48mm Group B
DYNASTY® BIOFOAM® Solid Shells (cleared under K122382)	
DBSSGB46	DYNASTY® BIOFOAM® solid shell 46mm Group B
DBSSGB48	DYNASTY® BIOFOAM® solid shell 48mm Group B
DYNASTY® BIOFOAM® 5 Hole Shells (cleared under K122382)	
DBF5GB46	DYNASTY® BIOFOAM® 5 hole shell 46mm Group B
DBF5GB48	DYNASTY® BIOFOAM® 5 hole shell 48mm Group B
DYNASTY® BIOFOAM® 3 Hole Quad Shells (cleared under K082924)	
DSBFGB46	DYNASTY® BIOFOAM® 3 hole Quad 46mm Group B
DSBFGB48	DYNASTY® BIOFOAM® 3 hole Quad 48mm Group B
DYNASTY® Acetabular Shells	
DSPCGB46	DYNASTY® 3-hole shell 46mm Group B
DSPCGB48	DYNASTY® 3-hole shell 48mm Group B
DYNASTY® A-CLASS® Poly Acetabular Liners	
DLXPGB28	DYNASTY® 28mm Group B Liner Standard
DLXPLB28	DYNASTY® 28mm Group B Liner 15 Lipped
Biolox Delta Femoral Heads	
PHA04402	Biolox Delta SLT 28mm Short
PHA04404	Biolox Delta SLT 28mm Medium
PHA04406	Biolox Delta SLT 28mm Long

Instrument Kit Parts List

Cleared under K122382

(Items in red are used with subject devices)

DNFLKIT1

Item Number	Description
General	
33330002	DYNASTY® SCREWDRIVER
Specialized	
3300GE54	DYNASTY® TRIAL SHELL GROUP E 54MM OD
3300GF56	DYNASTY® TRIAL SHELL GROUP F 56MM OD
3300GG58	DYNASTY® TRIAL SHELL GROUP G 58MM OD
3300GG60	DYNASTY® TRIAL SHELL GROUP G 60MM OD
41103200	DYNASTY® HEAD TRIAL 32MM
41103600	CONSERVE® TOTAL HEAD TRIAL 36MM
41104000	CONSERVE® TOTAL HEAD TRIAL 40MM
33330010	DYNASTY® SHELL IMPACTOR STRAIGHT OVERMOLD
33330020	DYNASTY® LINER IMPACTOR STRAIGHT OVERMOLD
33330040	DYNASTY® LINER IMPACTOR CURVED OVERMOLD
33330050	DYNASTY® LINER EXTRACTOR GROUP C 50MM OD
33330052	DYNASTY® LINER EXTRACTOR GROUP D 52MM OD
33330054	DYNASTY® LINER EXTRACTOR GROUP E 54MM OD
33330056	DYNASTY® LINER EXTRACTOR GROUP F 56MM OD
33330058	DYNASTY® LINER EXTRACTOR GROUP G 58MM OD
33330064	DYNASTY® LINER EXTRACTOR GROUP H 64-66-68MM OD
33330015	DYNASTY® TRIAL HEAD IMPACTOR
41102800	DYNASTY® HEAD TRIAL 28MM
DNALTRA1	DYNASTY® ALPHA TRAY
DNFLTRA1	DYNASTY® FULL LAUNCH TRAY

Instrument Kit Parts List

Cleared under K122382

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DNFLKIT1

Item Number	Description
Specialized	
3304GB28	DYNASTY® STD POLY TRIAL LINER GROUP B 28MM
3304GC32	DYNASTY® STD POLY TRIAL LINER GROUP C 32MM
3304GD36	DYNASTY® STD POLY TRIAL LINER GROUP D 36MM
3304GE36	DYNASTY® STD POLY TRIAL LINER GROUP E 36MM
3304GE38	DYNASTY® STD POLY TRIAL LINER GROUP E 38MM
3304GF36	DYNASTY® STD POLY TRIAL LINER GROUP F 36MM
3304GF40	DYNASTY® STD POLY TRIAL LINER GROUP F 40MM
3304GG42	DYNASTY® STD POLY TRIAL LINER GROUP G 42MM
3304GH36	DYNASTY® STD POLY TRIAL LINER GROUP H 36MM
3304GH46	DYNASTY® STD POLY TRIAL LINER GROUP H 46MM
3304GJ36	DYNASTY® STD POLY TRIAL LINER GROUP J 36MM
3304GK36	DYNASTY® STD POLY TRIAL LINER GROUP K 36MM
3304LB28	DYNASTY® 15DG POLY TRIAL LINER GROUP B 28MM
3304LC32	DYNASTY® 15DG POLY TRIAL LINER GROUP C 32MM
3304LD36	DYNASTY® 15DG POLY TRIAL LINER GROUP D 36MM
3304LE36	DYNASTY® 15DG POLY TRIAL LINER GROUP E 36MM
3304LE38	DYNASTY® 15DG POLY TRIAL LINER GROUP E 38MM
3304LF36	DYNASTY® 15DG POLY TRIAL LINER GROUP F 36MM
3304LF40	DYNASTY® 15DG POLY TRIAL LINER GROUP F 40MM
3304LG36	DYNASTY® 15DG POLY TRIAL LINER GROUP G 36MM
3304LH36	DYNASTY® 15DG POLY TRIAL LINER GROUP H 36MM
3304LJ36	DYNASTY® 15DG POLY TRIAL LINER GROUP J 36MM
3304LK36	DYNASTY® 15DG POLY TRIAL LINER GROUP K 36MM
33330001	DYNASTY® TRIAL LINER SCREW
33330080	DYNASTY® ALIGNMENT GUIDE STRAIGHT HANDLE 20 DEGREE
33330085	DYNASTY® ALIGNMENT GUIDE CURVED HANDLE 20 DEGREE
3300GB46	DYNASTY® TRIAL SHELL GROUP B 46MM OD
3300GB48	DYNASTY® TRIAL SHELL GROUP B 48MM OD
3300GG62V1	DYNASTY® TRIAL SHELL GROUP G 62MM OD
3300GH64V1	DYNASTY® TRIAL SHELL GROUP H 64MM OD
3300GH66V1	DYNASTY® TRIAL SHELL GROUP H 66MM OD
3300GH68V1	DYNASTY® TRIAL SHELL GROUP H 68MM OD
33330046	DYNASTY® LINER EXTRACTOR GROUP B 46-48MM OD
33330052	DYNASTY® LINER EXTRACTOR GROUP D 52MM OD
33330054	DYNASTY® LINER EXTRACTOR GROUP E 54MM OD
33330056	DYNASTY® LINER EXTRACTOR GROUP F 56MM OD
33330058	DYNASTY® LINER EXTRACTOR GROUP G 58MM OD
33330064	DYNASTY® LINER EXTRACTOR GROUP H 64-66-68MM OD
33330015	DYNASTY® TRIAL HEAD IMPACTOR

Instrument Kit Parts List

Cleared under K122382

(Items in red are used with subject devices)

DNFLKIT2

Item Number	Description
Specialized	
3300GJ70	DYNASTY® TRIAL SHELL GROUP J 70MM OD
3300GJ72	DYNASTY® TRIAL SHELL GROUP J 72MM OD
3300GJ74	DYNASTY® TRIAL SHELL GROUP J 74MM OD
3300GK76	DYNASTY® TRIAL SHELL GROUP K 76MM OD
3304GJ50	DYNASTY® STD POLY TRIAL GROUP J 50MM ID
3304GK54	DYNASTY® STD POLY TRIAL GROUP K 54MM ID
33330070	DYNASTY® LINER EXTRACTOR GROUP J 70-74MM OD
33330076	DYNASTY® LINER EXTRACTOR GROUP K 76MM OD
41105000	CONSERVE® TOTAL HEAD TRIAL 50MM
41105400	CONSERVE® TOTAL HEAD TRIAL 54MM

8400KIT1

Item Number	Description
General	
8400FD04	F LEX DRILL BIT 3.2 X 15MM
8400FD05	FLEX DRILL BIT 3.2 X 25MM
8400FD06	FLEX DRILL BIT 3.2 X 35MM
8400FD07	FLEX DRILL BIT 4.5 X 15MM
8400FD08	FLEX DRILL BIT 4.5 X 25MM
8400FD09	FLEX DRILL BIT 4.5 X 35MM
8400FD10	FLEX DRILL BIT 4.5 X 45MM
8400SD02	HEX HEAD SCREWDRIVER BIT MODULAR
8400SD03	UNIVERSAL JOINT 3.5MM HEX DRIVER SHFT W/STRYKER FIT
8400SD04	BALL & SOCKET 3.5MM HEX DRVR SHFT STR SOL W/STRYK
8400SD06	HEX DRIVER SHAFT W/STRYKR STRAIGHT SOLID 3.5MM
8400ST01	SCREW TAP MODULAR 6.5 X 15MM
8400ST02	SCREW TAP MODULAR 6.5 X 25MM
8400ST03	SCREW TAP MODULAR 6.5 X 35MM
2002QCRH	QUICK CONNECT RACHET HANDLE
Specialized	
4820SH0000	INTERSEAL® SCREW HOLDER
8400DG01	LINEAGE® FIXED ANGLE DRILL GUIDE 3.2mm/4.5mm
8400DG03	ADJUSTABLE DRILL GUIDE
8400FD01	FLEXIBLE DRILL SCREW SHAFT MODULAR
8400FD02	FLEX DRILL 3.2 X 25MM ONE PIECE
8400FD03	FLEX DRILL 4.5 X 25MM ONE PIECE
8400SG01	ADJUSTABLE SCREW DEPTH GAUGE
84003000	LINEAGE® ACETABULAR SCREW INSTRUMENT CASE

Instrument Kit Parts List

Cleared under K122382

2001KIT5

Item Number	Description
Specialized	
20010400	ACETABULAR REAMER HANDLE PRECIMED® DESIGN
20010441	ACETABULAR REAMER PRECIMED® DESIGN 41MM
20010442	ACETABULAR REAMER PRECIMED® DESIGN 42MM
20010443	ACETABULAR REAMER PRECIMED® DESIGN 43MM
20010444	ACETABULAR REAMER PRECIMED® DESIGN 44MM
20010445	ACETABULAR REAMER PRECIMED® DESIGN 45MM
20010446	ACETABULAR REAMER PRECIMED® DESIGN 46MM
20010447	ACETABULAR REAMER PRECIMED® DESIGN 47MM
20010448	ACETABULAR REAMER PRECIMED® DESIGN 48MM
20010449	ACETABULAR REAMER PRECIMED® DESIGN 49MM
20010450	ACETABULAR REAMER PRECIMED® DESIGN 50MM
20010451	ACETABULAR REAMER PRECIMED® DESIGN 51MM
20010452	ACETABULAR REAMER PRECIMED® DESIGN 52MM
20010453	ACETABULAR REAMER PRECIMED® DESIGN 53MM
20010454	ACETABULAR REAMER PRECIMED® DESIGN 54MM
20010455	ACETABULAR REAMER PRECIMED® DESIGN 55MM
20010456	ACETABULAR REAMER PRECIMED® DESIGN 56MM
20010457	ACETABULAR REAMER PRECIMED® DESIGN 57MM
20010458	ACETABULAR REAMER PRECIMED® DESIGN 58MM
20010459	ACETABULAR REAMER PRECIMED® DESIGN 59MM
20010460	ACETABULAR REAMER PRECIMED® DESIGN 60MM
20010461	ACETABULAR REAMER PRECIMED® DESIGN 61MM
20010462	ACETABULAR REAMER PRECIMED® DESIGN 62MM
20010463	ACETABULAR REAMER PRECIMED® DESIGN 63MM
20010464	ACETABULAR REAMER PRECIMED® DESIGN 64MM
20010465	ACETABULAR REAMER PRECIMED® DESIGN 65MM
20010466	ACETABULAR REAMER PRECIMED® DESIGN 66MM
20010467	ACETABULAR REAMER PRECIMED® DESIGN 67MM
20010468	ACETABULAR REAMER PRECIMED® DESIGN 68MM
4400DA0100	HALL/HUDSON ADAPTOR HALL HANDLE/HUDSON END
84002001	LINEAGE® ACETABULAR BOTTOM INSERT 62-80 (1MM)
84002003	LINEAGE® ACETABULAR OUTSIDE CASE W/ LID
84002004	LINEAGE® ACETABULAR TOP INSERT 40-61 (1MM) W/ HANDLE/ADAPTOR
20010440	ACETABULAR REAMER PRECIMED® DESIGN 40MM

Instrument Kit Parts List

Cleared under K122382

2006KIT1

Item Number	Description
Specialized	
20010400	ACETABULAR REAMER HANDLE PRECIMED® DESIGN
48000040	HEMISPHERICAL REAMER SIZE 40
48000041	HEMISPHERICAL REAMER SIZE 41
48000042	HEMISPHERICAL REAMER SIZE 42
48000043	HEMISPHERICAL REAMER SIZE 43
48000044	HEMISPHERICAL REAMER SIZE 44
48000045	HEMISPHERICAL REAMER SIZE 45
48000046	HEMISPHERICAL REAMER SIZE 46
48000047	HEMISPHERICAL REAMER SIZE 47
48000048	HEMISPHERICAL REAMER SIZE 48
48000049	HEMISPHERICAL REAMER SIZE 49
48000050	HEMISPHERICAL REAMER SIZE 50
48000051	HEMISPHERICAL REAMER SIZE 51
48000052	HEMISPHERICAL REAMER SIZE 52
48000053	HEMISPHERICAL REAMER SIZE 53
48000054	HEMISPHERICAL REAMER SIZE 54
48000055	HEMISPHERICAL REAMER SIZE 55
48000056	HEMISPHERICAL REAMER SIZE 56
48000057	HEMISPHERICAL REAMER SIZE 57
48000058	HEMISPHERICAL REAMER SIZE 58
48000059	HEMISPHERICAL REAMER SIZE 59
48000060	HEMISPHERICAL REAMER SIZE 60
48000061	HEMISPHERICAL REAMER SIZE 61
48000062	HEMISPHERICAL REAMER SIZE 62
48000063	HEMISPHERICAL REAMER SIZE 63
48000064	HEMISPHERICAL REAMER SIZE 64
48000065	HEMISPHERICAL REAMER SIZE 65
48000066	HEMISPHERICAL REAMER SIZE 66
48000067	HEMISPHERICAL REAMER SIZE 67
48000068	HEMISPHERICAL REAMER SIZE 68
84002001	LINEAGE® ACETABULAR BOTTOM INSERT 62-80 (1MM)
84002003	LINEAGE® ACETABULAR OUTSIDE CASE W/ LID
84002004	LINEAGE® ACETABULAR TOP INSERT 40-61 (1MM) W/ HANDLE/ADAPTOR

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MH100-113

HIP SYSTEM

136288-x

The following languages are included in this packet:

English (en)	Deutsch (de)	Nederlands (nl)	Français (fr)
Español (es)	Italiano (it)	Português (pt)	中文-Chinese (sch)
Türkçe (tk)			

For additional languages, visit our website www.wmt.com

Then click on the **Prescribing Information** option.

For additional information and translations please contact the manufacturer or local distributor.

CE 0086*

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EC REP

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The Netherlands

*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

℞ ONLY

May 2013
Printed in U.S.A.

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

HIP SYSTEM

(136288-x)

OUTLINE

HIP GENERAL INFORMATION

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
LOT	Batch code
REF	Catalog number

	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
EC REP	Authorized EC Representative in the European Community
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using radiation
STERILE GAS	Sterilized using gas plasma
℞ ONLY	Caution: U.S. federal law restricts this device to sale by or on the order of a physician
	Do not use if package is damaged
Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
Al_2O_3	Alumina
ZrO_2	Zirconia
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
$CaSO_4$	Calcium Sulfate
HA	Hydroxyapatite
PMMA	Polymethylmethacrylate
PDLLA	Poly D, L-Lactic Acid
PDMS	Silicone 55D

DESCRIPTION

Wright Medical Technology, Inc has a variety of hip joint replacement prostheses. The components for these systems include an acetabular shell, acetabular liner, fixation screws, femoral head, femoral stem, modular neck and a proximal body. These components can be utilized in a variety of configurations to assemble the final construct. Only components from Wright should be used to prevent mismatch or misalignment of components.

The femoral, acetabular, and cement restrictor components are manufactured from a variety of

materials which include cobalt-chromium-molybdenum alloy, titanium alloy, unalloyed titanium, Alumina ceramic (Biolox Forte diameters 28-36mm; and diameters 38-54mm "Conserve® Total BCH® Femoral Head"), Alumina Matrix Composite ceramic (Biolox Delta), hydroxyapatite, calcium sulfate, polymethylmethacrylate (PMMA), Poly D,L-Lactic Acid (PDLLA), silicone (PDMS) 55D, and ultra high molecular weight polyethylene (UHMWPE), all of which conform to ASTM or ISO standards, or internal standards. See Table 1.

The implants are single use only devices.

A. GENERAL PRECAUTIONS

Preoperative Precautions

The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection. The surgeon must be thoroughly familiar with the implant, instruments and surgical procedure prior to performing surgery. The surgeon should contact Wright for product-specific surgical techniques.

Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. Implant longevity and stability may be affected by these variables. A heavy-weight patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis. The surgeon must consider the ability and willingness of the patient to follow instructions and to control their weight and activity level. Patients with high activity levels, poor bone quality, or heavyweight patients may not be candidates for a narrower femoral implant. Any joint replacement system, including the implant/bone interface, cannot be expected to withstand activity levels and loads as would normal healthy bone and will not be as strong, reliable, or durable as a natural human joint. The patient should not have unrealistic functional expectations for occupations or activities that include substantial walking, running, lifting, or muscle strain.

Additional conditions presenting increased risk of failure include:

1) uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2) marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
3) metabolic disorders that may impair bone formation;
4) osteomalacia;
5) poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition);
6) pre-existing conditions commonly considered with any surgery including bleeding disorders, long-term steroidal therapy, immunosuppressive therapy, or high dosage radiation therapy.

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the

prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life, and may need to be replaced at some time in the future. The patient should also be advised of other risks that the surgeon believes should be disclosed. The patient should be advised that any noise or unusual sensation should be reported to the surgeon as it may indicate implant malfunction.

Intraoperative Precautions

Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components. Do not mix instruments from different manufacturers. While rare, breakage of instruments may occur especially with extensive use or excessive force. For this reason, instruments should be examined for wear or damage prior to surgery.

Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.

Correct selection of the prosthesis is extremely important. Joint prostheses require careful seating and adequate bone support. Surgeons are encouraged to use their best medical judgment when choosing the proper implant size regardless of the endosteal area of the bone. Proper implant selection must consider design, fixation, patient weight, age, bone quality, size, activity level, preoperative level of health, and also the surgeon's experience and familiarity with the device. Implant longevity and stability may be affected by these variables. Surgeons should inform the patient about these factors.

X-ray templates are used to estimate the size of the product to be used. The anatomy of the patient ultimately determines the size of the product for an individual patient. The extent of bone preparation is determined intraoperatively by reaming and/or broaching starting at the smallest size and continuing until bleeding cancellous bone is reached. Trial prostheses should be used to evaluate the position of the final implant and the joint range of motion. The final size of the implant selected during surgery may differ from the size originally planned during preoperative assessment or the combination chosen during preliminary trialing.

Cemented Application. Care is to be taken to ensure complete support of all components of the prosthesis embedded in bone cement to prevent stress concentrations that may lead to failure of the procedure. Complete cleaning including complete removal of bone chips, bone cement fragments, and metallic debris, prior to closure of the prosthetic site is critical to prevent accelerated wear of the articular surfaces of the prosthesis. The PMMA Distal Centralizers are intended for use as part of a cemented total hip arthroplasty.

Non-Cemented Application**.** Adequate fixation at the time of surgery is critical to the success of the procedure. Uncemented femoral stems and acetabular shells must press fit into the host bone, which necessitates precise operative technique and the use of specified instruments. Bone stock must be adequate to support the device.

Postoperative Precautions

The patient must be advised of the limitations of the reconstruction and the need for protection of the prosthesis from full weight bearing until adequate fixation and healing have occurred. The patient should be cautioned to limit activities and protect the replaced joint from unreasonable stresses and possible loosening, fracture and/or wear, and follow the instructions of the physician with respect to follow-up care and treatment. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone. Periodic post-operative x-rays are recommended for close comparison with early post-op conditions to detect long term evidence of changes in position, loosening, bending, or cracking of components.

Recommendations Regarding Device Fragments

1. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
2. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
3. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
4. Advise the patient of the nature and safety of unretrieved device fragments including the following information:
    a. The material composition, size, and location of the fragment (if known);
    b. The potential mechanisms for injury, e.g., migration, infection;
    c. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

There are inherent risks associated with the use of metallic implants in the MR environment; including component migration, heat induction, and signal interference or distortion near the component(s). Heat induction of metallic implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants.

Wright Hip Systems have not been evaluated for safety and compatibility in the MR environment. Wright Hip Systems have not been tested for heating or migration in the MR environment. Since these devices have not been tested, Wright cannot make a recommendation for the use of MRIs with these implants, neither for safety considerations nor imaging accuracy.

These components are passive metallic devices, and as with all passive devices, there is potential for reciprocal interference with certain imaging modalities; including image distortion for MR and X-ray scatter in CT.

B. ADVERSE EFFECTS for total hip arthroplasty implants can include:

1) Osteolysis (progressive bone resorption). Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is vital to prevent any serious future complication.
2) Particulates leading to increased wear rates necessitating early revision.
3) Allergic reactions to materials; metal sensitivity that may lead to histological reactions, pseudotumor and aseptic lymphocytic vasculitis-associated lesions (ALVAL).
4) Delayed would healing; Deep wound infection (early or late) which may necessitate removal of the prosthesis. On rare occasions, arthrodesis of the involved joint or amputation of the limb may be required.
5) A sudden drop in blood pressure intra-operatively due to the use of bone cement;
6) Damage to blood vessels or hematoma;
7) Temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as possible result of surgical trauma resulting in pain or numbness of the affected limb;
8) Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
9) Fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, incomplete implant seating, duration of service, loss of fixation, non-union, or excessive weight;
10) Dislocation, migration and/or subluxation of prosthetic components from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity;
11) Periarticular calcification or ossification, with or without impediment to joint mobility;
12) Trochanteric non-union due to inadequate reattachment and or early weight bearing;
13) Trochanteric avulsion as a result of excess muscular tension, early weight bearing, or inadvertent intraoperative weakening;
14) Traumatic arthrosis of the knee from intraoperative positioning of the extremity;
15) Inadequate range of motion due to improper selection or positioning of components, by femoral impingement, and periarticular calcification;
16) Femoral or acetabular perforation or fracture; femoral fracture while seating the device; femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
17) Undesirable shortening or lengthening of the limb;
18) Aggravated problems of the affected limb or contralateral extremity by leg length discrepancy, excess femoral medialization, or muscle deficiency;
19) Pain.

C. HANDLING AND STERILIZATION

Implants

Implants are sterilized by gamma radiation, ethylene oxide, or gas plasma. The immediate package label should be consulted for specific method of sterilization. Irradiated implants have been exposed to a minimum 25 and a maximum 40 kiloGrays of gamma radiation.

Unless supplied non-sterile, this product has been sterilized and should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the manufacturer for instructions. Remove from package, using aseptic OR technique, only after the correct size has been determined and the operative site has been

prepared for final implantation. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product. This is particularly important in handling porous coated and HA coated prostheses. Do not allow porous surfaces or HA surfaces to come in contact with cloth or other fiber releasing materials.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

A prosthesis should never be resterilized or reused after contact with body tissues or fluids, but rather should be discarded. Wright does not take any responsibility for the use of implants resterilized after contact with body tissues or fluids.

WARNINGS:

- All packaging materials MUST be removed from the implant prior to implantation.
- Do not sterilize femoral prostheses with ceramic femoral heads seated on the stem.
- You must **NEVER** steam sterilize ceramic, HA, calcium sulfate, plastic, and/or metal/plastic implants. If steam sterilization of the metal component(s) is required, proceed as described below.

Instruments

Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove any gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. **Rinse** thoroughly /flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Sterilization

The minimum recommended steam sterilization conditions for Wright reusable instruments are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 270˚F (132˚C)	Exposure Temperature	270˚F (132˚C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with ANSI/AAMI ST79: 2006 Table 5 guidelines[1] and have been developed and validated using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

For additional information regarding instruments, see Wright's Cleaning and Handling of Wright Instruments.

D. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature. Calcium sulfate coated implants should be stored at 15°C/59°F – 30°C/86°F.

CAUTION: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

HIP FEMORAL SYSTEM

E. INDICATIONS

Intended Use

Wright total hip systems are intended for use in total hip arthroplasty for reduction or

1 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2006)

relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use
1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed

Rough grit blast surfaces and the hydroxyapatite, titanium plasma spray, and calcium sulfate coatings applied to implant surfaces are intended for uncemented arthroplasty.

Limb Salvage System is indicated for procedures where radical resection and replacement of the proximal, distal and/or total femur is required with the following conditions:
1) patients suffering from severe arthropathy of the hip that does not respond to any conservative therapy or better alternative surgical treatment;
2) surgical intervention for severe trauma, revision hip arthroplasties, and/or Oncology indications;
3) metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors).

Ultime Hip Stem (not available in the U.S. or Canada) is indicated for the following conditions:
1) revision after stem loosening in cases of proximal bone loss (Paprosky grade III and IV);
2) peri-prosthetic femoral fractures; and,
3) major bone loss due to tumor cases or revision of previous massive prosthesis.

F. CONTRAINDICATIONS

Patients should be warned of these contraindications.
Contraindications include:
1) overt infection;
2) distant foci of infections (which may cause hematogenous spread to the implant site);
3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
4) skeletally immature patients (patient is less than 21 years of age at the time of surgery);
5) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
6) neuropathic joints;
7) hepatitis or HIV infection;
8) neurological or musculoskeletal disease that may adversely affect gait or weight-bearing.

Additional contraindications for the calcium sulfate coated implants include:
1) severe vascular or neurological disease;
2) uncontrolled diabetes;
3) severe degenerative bone disease;

4) pregnancy;
5) hypercalcemia;
6) renal compromised patients;
7) patients with a history of or active Pott's disease; and,
8) where intraoperative soft tissue coverage is not planned or possible.

G. PRODUCT-SPECIFIC WARNINGS AND PRECAUTIONS

NEVER combine these metals in NON-ARTICULATING contact surfaces:

- Stainless steel (excluding the stainless steel described in ISO 5832-9)/cobalt chrome alloy
- Stainless steel (excluding the stainless steel described ISO 5832-9)/titanium alloy.
- Stainless steel (excluding the stainless steel described ISO 5832-9)/unalloyed titanium.

Do not attempt to seat the implant beyond the envelope of femoral bone preparation. Forcing to seat the implant beyond the prepared femoral bone may increase the chance of bone fracture. In some cases, a portion of the proximal body with or without coating may be visible above the proximal resection level.

The smaller sized femoral implants are intended for patients with narrower intramedullary femoral canals. The geometry of these implants is reduced to accommodate the anatomy of the narrower intramedullary femoral canal, which also decreases the fatigue-strength and load-bearing characteristics of the implant.

Other **Modular Components** (Femoral Head and Stems, Modular Necks and Proximal Body). Scratching of femoral heads, modular necks and proximal and distal stem tapers should be avoided. Repeated assembly and disassembly of these components could compromise the locking action of the taper joint. Prior to assembly, surgical debris must be cleaned from the interior of the female seat of the proximal body to ensure proper locking. Ensure components are firmly seated to prevent disassociation. The femoral head, neck taper of the femoral component, modular neck tapers, body taper, female seat of the proximal body **must** be clean and dry before assembly. Do not resterilize femoral prostheses with ceramic femoral heads seated on the stem. Please refer to the section below named Hip Bearing System for specific warnings and precautions regarding ceramic femoral heads.

Please refer to the corresponding surgical technique and package labels for allowable device combinations.

Stems and modular necks with the Wright 12/14 SLT Taper should only be used in combination with femoral heads with the Wright 12/14 SLT Taper. Cobalt chrome femoral heads with the Wright 12/14 SLT Taper are designed for use with cobalt-chromium-molybdenum, titanium alloy and (ISO 5832-9) stainless steel (not available in the U.S. or Canada) femoral components with the 12/14 SLT Taper.

The neck/body component or neck/femoral stem should be changed only when clinically necessary. Refer to proper neck extraction technique in the surgical technique.

PROFEMUR® A^M Stems. (Not available in the U.S. or Canada)

- PROFEMUR® A^M Size 1 stems are only intended for patients weighing less than 60kg.
- 15° Varus Modular Necks, both Long and Short, are not for use with the PROFEMUR® A^M Size 1 and Size 2 Stems

PROFEMUR® Plasma Z, PROFEMUR® GLADIATOR®, and PROFEMUR® E modular stems in the U.S. are only intended for use with cobalt chrome modular necks.

PROFEMUR® Preserve Stems are only intended for use with cobalt chrome modular necks.

Modular Necks.

- Higher than normal rates of early failure of the long offset PROFEMUR® Titanium Modular Necks have been observed for heavyweight (>230 lbs) patients. This should be considered in patient selection when using these implants. Other patient selection factors such as activity level cannot be dismissed as potential factors in these failures. Alternative devices, such as cobalt chrome modular necks and monoblock hip stems, may also be considered for these patients.

- Cobalt Chrome Modular Necks are not for use with the following devices:
  - Alumina (Biolox Forte) "Ceramic Femoral Head" (size 28mm Long)
  - PROFEMUR® E Size 0 hip stem

Neck Sleeves must only be used with femoral stems and necks having the 12/14 SLT Taper. The "CONSERVE® Total Neck Sleeve" size 38NS0035 is not intended for use with GLADIATOR® Classic, Preserve size 0, or Z size 0 monolithic hip stems (Stem designs may not be available yet in the U.S. or Canada).

Ultime Hip Stem. (Not available in the U.S. or Canada) Success depends on proximal bone reconstruction and correct distal fixation (as also explained within the device surgical technique):

- In the case of massive proximal bone loss it is recommended to provide perfect metaphyseal stability to the implant and achieve optimal bone reconstruction, by means of grafting and/or bone substitute.
- To avoid damaging the first proximal hole, it is recommended to avoid drilling or fixating this hole before having drilled and fixed the other distal holes, to prevent jeopardizing its functionality.
- At the moment of the closure, metallic monofilament cerclages are recommended to allow solid fixation of the flap on the implant.
- Progressive weight-bearing must begin only in the presence of good proximal femoral reconstruction (partial loading with crutches)

Adverse effects for calcium sulfate coated implants can include:

1) wound complications including hematoma, site drainage, bone fracture, infection, and other complications that are possible with any surgery;
2) fracture or extrusion of the bone void filler, with or without particulate debris generation;
3) deformity of the bone at the site;
4) incomplete, or lack of, osseous ingrowth into bone void, as is possible with any bone void filler;
5) transient hypercalcemia;
6) potential to pressurize material in a closed void, which could result in fat embolization and/or embolization of the device material into the blood stream.

Calcium sulfate coated implants should be stored at 15°C/59°F – 30°C/86°F.

HIP BEARING SYSTEM

H. INDICATIONS

Intended Use

Wright total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed

Rough grit blast surfaces and the hydroxyapatite, titanium plasma spray, and calcium sulfate coatings applied to implant surfaces are intended for uncemented arthroplasty.
CONSERVE® shells are intended only for uncemented arthroplasty, with the exception of those shells possessing screw holes for additional screw fixation, which may be used in either cemented or uncemented arthroplasty. Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty. Modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.

The size 50 and 54mm alumina ceramic "CONSERVE® Total BCH® Femoral Heads"are only intended for patients with giganticism or malunion of the acetabulum, and/or revision.

Note: The "CONSERVE® Femoral Resurfacing Component/Head" is not cleared for use with an acetabular component in the U.S.

Hemi Resurfacing Femoral Component is indicated for use in resurfacing of the femoral head for reduction or relief of pain and/or improved hip function in skeletally mature patients with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia.

Hemi Unipolar Head is indicated for use in hemiarthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients, for replacement of the femoral head of the hip joint due to degenerative bone disease, trauma, non-union, or avascular necrosis.

Bipolar Hip System is indicated for the following conditions:
1) Pathological fractures of the femoral neck;
2) Non-union of femoral neck fractures;
3) Aseptic necrosis of the femoral head and neck; and,
4) Primary pathology in the young involving the femoral head but with a non deformed acetabulum.

I. CONTRAINDICATIONS

Patients should be warned of these contraindications.
Contraindications include:
1) overt infection;
2) distant foci of infections (which may cause hematogenous spread to the implant site);
3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
4) skeletally immature patients (patient is less than 21 years of age at the time of surgery);
5) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
6) neuropathic joints;
7) hepatitis or HIV infection;
8) neurological or musculoskeletal disease that may adversely affect gait or weight-bearing.

Additional contraindications for the "CONSERVE® Femoral Resurfacing Component/Head" include:
1) inflammatory degenerative joint disease;
2) severe osteopenia.

Additional contraindications for a metal-on-metal bearing include:
1) Patients with known moderate to severe renal insufficiency;
2) Females of childbearing age are contraindicated due to the unknown effects of elevated levels of metal ions on the fetus.

J. PRODUCT-SPECIFIC WARNINGS AND PRECAUTIONS

The potential long-term biological effects of metal wear debris and metal ion production are not known. Questions regarding carcinogenicity have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

Please refer to the corresponding surgical technique and package labels for allowable device combinations.

NEVER combine modular or hard bearing components made by different manufacturers. Metal/metal and ceramic/ceramic[3] articulating combinations should only combine bearing components from a single manufacturer to ensure the two components possess compatible manufacturing tolerances. [In the U.S., the only approved ceramic/ceramic[3] combination is the alumina (Biolox Forte) "LINEAGE® Ceramic Liners" in assembly with the corresponding 28-36mm diameter alumina (Biolox Forte) "Ceramic Femoral Head".]

In the U.S., the "DYNASTY® A-CLASS® Poly (UHMWPE) Liners" are designed to articulate with the following ceramic femoral heads:

- Alumina "Ceramic Femoral Head" (Biolox Forte diameters 28-36mm)
- Alumina "CONSERVE® Total BCH® Femoral Head" (diameter range 38-54mm)
- "Alumina Matrix Composite" (Biolox Delta) ceramic heads (diameter range 28-40mm)

Additionally in the U.S., the Alumina "Ceramic Femoral Head" (Biolox Forte) are designed to articulate with "LINEAGE® DURAMER®" and "LINEAGE® A-CLASS®" UHMWPE polyethylene acetabular liners (diameters 28-36mm).

Outside the U.S., **alumina ceramic (Biolox Forte)** acetabular liners are designed for use with the following Biolox ceramic femoral heads (manufactured by CeramTec and packaged by Wright):

- Alumina "Ceramic Femoral Head"
- Alumina "Biolox Forte Femoral Head"
- Alumina Matrix Composite Ceramic Heads: "Biolox Delta Femoral Head"

Outside the U.S., **Alumina Matrix Composite (Biolox Delta) acetabular liners** are designed for use with the following ceramic femoral heads (manufactured by CeramTec and packaged by Wright):

- Alumina Matrix Composite Ceramic Heads: "Biolox Delta Femoral Head"

Ceramic femoral heads and **acetabular liners**[3] should not be placed on scratched or previously assembled metal tapers as this may lead to a ceramic fracture.

Fracture of ceramic components is a serious complication. Special care must be taken with ceramic devices, which must not be used if dropped, even in the absence of any apparent damage. Only use a plastic tip to introduce the ceramic devices. Patients should be advised to

3 Please see the additional package insert addressing ceramic-on-ceramic articulation.

report unusual noise and/or sharp pain as both can be an indication of fracture. Decision to revise should not be postponed as ceramic fragments can cause severe damage to surrounding soft tissue and metal components. Revision outcomes after ceramic fractures can be compromised by the remaining ceramic debris present in the tissue even after careful debridement. Damage has been reported in polyethylene and metal components used in revisions after ceramic fractures. Surgeons are advised to carefully consider all available implant options on an individual basis. It must be noted that removal of all components including femoral stems and acetabular shells may not prevent accelerated wear due to ceramic debris in the tissue. Partial or complete synovectomy has been recommended by some authors.

Acetabular Fixation Screws. Perforation of the pelvis with dome fixation screws or rim screws is to be completely avoided. Care is to be used when determining and selecting the proper length of screws to be used to prevent perforation of the pelvis.

Modular Acetabular Shell/Liner.

- Fixation screws, when used, should be fully seated to ensure stable fixation of the shell, and avoid interference with the liner component. Before implanting, be certain the selected shell and liner are compatible. Prior to seating the liner component into the shell component, surgical debris must be cleaned from the interior of the shell and the shell must be thoroughly dried. Debris and fluid may inhibit the liner from locking into the shell component. Failure to properly seat the liner into the shell can lead to disassociation of the liner from the shell.
- **Note:** There is currently no clinical evidence supporting the long term use of large diameter femoral heads with cross-linked polyethylene liners.

In order to prevent mismatch of tapers:

- Modular liners from Wright Medical Technology, Inc (Wright) must be used only with shell components of the same system from Wright.
- An exception to this rule is that all Wright 18° taper liner components can be used with 18° modular acetabular shells.

Conditions presenting increased risk of failure for the "**CONSERVE® Femoral Resurfacing Component/Head"** include:

1) significant leg length discrepancy; and,
2) presence of multiple cysts in the femoral head.

CONSERVE® Shells. In the U.S., these shells are only to be used with the following CONSERVE® Heads:

- "CONSERVE® BFH® Head" with the SLT taper
- "CONSERVE® A-CLASS® BFH® Head" with the SLT taper

"CONSERVE® Total A-CLASS® Femoral Head" with the SLT taper

In international markets (other than the U.S.) , the use of the CONSERVE® family of shells

("CONSERVE® Thick Shells", "CONSERVE® Thin Shells", "CONSERVE® Spiked Shells", "CONSERVE® SUPER-FIX® Shells", "CONSERVE® QUADRA-FIX® Shells", and "CONSERVE® HA Shells") are approved for use with the "CONSERVE® Femoral Resurfacing Components/Heads" and "CONSERVE® A-CLASS® Femoral Resurfacing Heads".

The "**CONSERVE® Total Neck Sleeves"** are only indicated for use with the "CONSERVE® Total BCH® Femoral Heads" or the following "CONSERVE® Total A-CLASS® Femoral Heads". These femoral heads are indicated for mandatory use with these modular neck sleeves. Neck sleeves must only be used with femoral stems and necks having the 12/14 SLT Taper.

Metal BFH® Femoral Heads for mandatory use with "**CONSERVE® Total Neck Sleeves"**:

38AC3600	38AC4400	38AC5200	38AC6000
38AC3800	38AC4600	38AC5400	
38AC4000	38AC4800	38AC5600	
38AC4200	38AC5000	38AC5800	

(Sizes 58 and 60 are not available in the U.S. or Canada)

"**CONSERVE® Total Neck Sleeve"** size 38NS0035 is not intended for use with GLADIATOR® Classic, Preserve size 0, or Z size 0 monolithic hip stems (Stem designs may not be available yet in the U.S. or Canada).

Cross-linked "DYNASTY® A-CLASS® Poly Liners" are to be used with ceramic heads or the following metal heads. The **Wright 18˚ taper metal liners** are to be used only with the following superfinished Wright metal heads:

- "LINEAGE®/TRANSCEND® Femoral Head" SuperFinished CoCr with the SLT taper
- "CONSERVE® BFH® Head" with the SLT taper
- "CONSERVE® A-CLASS® BFH® Head" with the SLT taper
- "CONSERVE® Total A-CLASS® Femoral Head" with the SLT taper

The size 28mm Long Neck **alumina (Biolox Forte) "Ceramic Femoral Heads"** are indicated for use only with titanium alloy femoral stems. All other sizes of the **alumina (Biolox Forte) "Ceramic Femoral Heads"** and all sizes of the Alumina Matrix Composite Heads ("Biolox Delta Femoral Head") are indicated for use with titanium alloy, cobalt chrome, or Wright stainless steel (not available in the U.S. or Canada) femoral stems.

Once a removal key has been used to disassociate a head from a **bipolar cup**, the head must be replaced to avoid potential scratch damage.

The following **collared/skirted femoral heads** and **bipolar cups** should **not** be used in combination together:

- "LINEAGE®/TRANSCEND® Femoral Head" (NECK LENGTH +7mm X-LONG)
- "Femoral Head" (NECK LENGTH +7mm X-LONG)
- "Femoral Head" (NECK LENGTH +10.5mm XX-LONG)

- “GLADIATOR® Bipolar”
- “SLR Bipolar Shell”
- “Bipolar Shell”

The cobalt-chromium-molybdenum, (ISO 5832-9) stainless steel, and the titanium femoral components with the Orthomet taper are designed for use with the **Orthomet taper femoral heads**, fabricated from cobalt-chromium-molybdenum alloy as indicated above:

Orthomet Taper Cobalt Chrome Femoral Heads:

- “Femoral Head” OMET Taper SuperFinished CoCr
- “Hemi Head” OMET Taper CoCr

These stems can also be used with the following **Zirconia Ceramic Femoral Heads** (not available in the U.S.): “Orthomet Taper Ceramic Femoral Heads”; “Femoral Head OMET Taper Zr.”

(b)(4)Trade Secret Process - Product Specs