Aesculap Implants Systems, LLC
Paul Amudala
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

March 28, 2018

Re: K172235
Trade/Device Name: CoreHip® 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, KWY
Dated: February 19, 2018
Received: February 20, 2018

Dear Paul Amudala:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172235

Device Name

CoreHip® System

Indications for Use *(Describe)*
The CoreHip® System is intended to replace a hip joint. The device is intended for:

• Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur
• Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
• Patients suffering from disability due to previous fusion
• Patients with acute femoral neck fractures

The CoreHip® System is available with two (2) types of femoral stem fixation. One stem is manufactured from CoCrMo and is intended for cemented fixation and the other femoral stem is manufactured from Ti with Plasmapore® and is intended for uncemented (pressfit) fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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B. 510(k) SUMMARY (as required by 21 CFR 807.92)

CoreHip® System

Mar 26, 2018

COMPANY: Aesculap Implant Systems, LLC
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Paul Amudala
610-984-9303 (phone)
610-791-6882 (fax)
paul.amudala@aesculapimplants.com

TRADE NAME: CoreHip® System

COMMON NAME: Femoral Hip Stem

REGULATION NUMBER: 888.3353-Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
888.3360-Hip joint femoral (hemi-hip) metal polymer cemented or uncemented prosthesis
888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.

PRODUCT CODE(S): LZO
SUBSEQUENT PRODUCT CODE(S): LWJ; KWY

REVIEW PANEL: **Orthopedics**

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC (AIS) believes that CoreHip® System is substantially equivalent to the Primary Predicate AIS Excia® Total Hip System (K150062 (including K140915, K092143, K090299, K081973, K082991, K062684, K061699, K061344, K060918, K060437, and K042344)) and Reference Predicate Zimmer Fitmore Knee System (Porolock MIS Stem) (K071723**).**

DEVICE DESCRIPTION

The CoreHip System includes cemented and uncemented (pressfit) stems. The CoreHip uncemented (pressfit) Stem is offered as CoreHip uncemented (pressfit) Primary and CoreHip uncemented (pressfit) Extended which are manufactured from Ti with a Ti plasma spray coating (Plasmapore®) proximally and rough-blasted distally. The Cemented Stem is offered as CoreHip Cemented Primary stem which is manufactured from CoCrMo. The CoreHip System includes stem variants of varus, neutral, valgus and dysplasia (dysplasia is offered in CoreHip uncemented (pressfit) Primary only), which have different medial curves in order to address different patient

morphologies. The femoral stems will be offered in a 12/14 external taper in stem sizes 1 to 11 for the uncemented (pressfit) design (primary (except size 1 dysplasia) and extended) and sizes 1-11 for the cemented design.

PURPOSE FOR PREMARKET NOTIFICATION

The purpose of this premarket notification is to gain clearance of CoreHip cemented and uncemented (pressfit) femoral System.

INDICATIONS FOR USE

The CoreHip® System is intended to replace a hip joint. The device is intended for:

- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

The CoreHip® System is available with two (2) types of femoral stem fixation. One stem is manufactured from CoCrMo and is intended for cemented fixation and the other femoral stem is manufactured from Ti with Plasmapore® and is intended for uncemented (pressfit) fixation.

TECHNOLOGICAL CHARACTERISTICS (compared to Predicate(s))

The addition of the CoreHip System to the AIS Hip portfolio is substantially equivalent to the Primary Predicate Excia® Total Hip System and the Reference Predicate Fitmore Hip System. The subject device has the same technological characteristics through comparison of the currently marketed stem, intended use, indications for use, materials of construction, manufacturing process, and range of sizes offered.

	CoreHip System (Principle)	Excia® Total System (Primary Predicate)	Fitmore Hip System (Reference Predicate)
K#	K172235	K150062 (including K140915, K092143, K090299, K081973, K082991, K062684, K061699, K061344, K060918, K060437, and K042344)	K071723
Manufacturer	Aesculap Implant Systems	Aesculap Implant Systems	ZimmerBiomet.
Indications	The CoreHip System is intended to replace a hip joint. The device is intended for: • Patients suffering from severe hip pain and disability due to	The Excia® Hip System is intended to replace the hip joint.	Zimmer Fitmore (Porolock MIS Stem) This femoral stem is for total or hemi-hip

	CoreHip System (Principle)	Excia® Total System (Primary Predicate)	Fitmore Hip System (Reference Predicate)
	rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur • Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis • Patients suffering from disability due to previous fusion • Patients with acute femoral neck fractures The CoreHip system is available with two (2) types of femoral stem fixation. One stem is manufactured from CoCrMo and is intended for cemented fixation and the other femoral stem is manufactured from Ti with Plasmapore® and is intended for uncemented (pressfit) fixation.	The device is intended for: • Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur • Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis • Patients suffering from disability due to previous fusion • Patients with acute femoral neck fractures The Excia Hip System is available with two(2) femoral stems. One is manufactured from CoCrMo and intended for cemented fixation. The other femoral stem is for	arthroplasty and is indicated for the following conditions: Patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory degenerative joint disease (IJD), e.g., rheumatoid arthritis; Those patients with failed previous surgery where pain, deformity, or dysfunction persists; Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient and modified demands regarding activity and hip joint loading are assured This includes severely crippled patients with multiple joint involvement , for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives. The stem is for cementless use only.

	CoreHip System (Principle)	Excia® Total System (Primary Predicate)	Fitmore Hip System (Reference Predicate)
		cementless fixation and is manufactured from Ti with Plasmapore or Without µCap®.	
Materials	The CoreHip System is available with two (2) types of femoral stem fixation. One stem is manufactured from CoCrMo and is intended for cemented fixation and the other femoral stem is manufactured from Ti with Plasmapore® and is intended for uncemented (pressfit) fixation.	The Excia® Hip System is available with two (2) types of femoral stem fixation. One stem is manufactured from CoCrMo and is intended for cemented fixation and the other femoral stem is manufactured from Ti with Plasmapore® with or without µCaP® and is intended for cementless fixation.	This femoral stem is available with one (1) type of femoral fixation. It is manufactured from Ti with Ti plasma spray and is intended for uncemented use only.
Bone Apposition	CoreHip uncemented (pressfit) Primary and CoreHip uncemented (pressfit) Extended Stems incorporate Plasmapore® a Ti –plasma spray coating proximally and rough-blasted surface distally. CoreHip cemented Primary incorporates the use of cement for fixation.	The Excia® Hip System cementless stems incorporate Plasmapore® a Ti –plasma spray coating proximally and smooth surface distally. The Excia® Hip System cemented stems incorporate the use of cement for fixation.	This femoral stem incorporates a Ti-Plasma spray coating proximally and rough-blasted surface distally.
12/14 Taper	12/14 Taper Only available	8/10 and 12/14 Tapers available	12/14 Taper Only available
Stem Offset	Dysplasia: 142° Neck Angle Valgus: 142° Neck Angle Standard/Neutral: 132° Neck Angle Varus: 122° Neck Angle Each provides a 7.5mm offset from the lesser neck angle	6mm from the lesser neck angle	Family A: 140° Family B: 137° Family B ext: 129° Family C: 127°
Standard/Neutral Neck Angle		135°	
Lateral Neck Angle		128°	

	CoreHip System (Principle)	Excia® Total System (Primary Predicate)	Fitmore Hip System (Reference Predicate)
Sterile, Single Use	Sterile, Single Use	Sterile, Single Use	Sterile, Single Use
Stem Sizes	CoreHip uncemented (pressfit) Primary : Sizes 1-11 (except size 1 dysplasia) CoreHip uncemented (pressfit) Extended: Sizes 1-11 CoreHip cemented Primary : Sizes 1-11	Excia 8/10 Trunnion cementless: Sizes 8-18 Excia 8/10 Trunnion cemented: Sizes 9-18 Excia 12/14 Trunnion cementless: Sizes 8-18 Excia 12/14 Trunnion cemented: Sizes 9-19 Excia T 12/14 Trunnion cementless: Sizes 8-20 Excia T 12/14 Trunnion cemented: Sizes 10-20 (even sizes only)	Family A: Sizes 2-8 Family B: Sizes 1-7 Family B ext: Sizes 1-7 Family C: Sizes 1-7
Centralizer	Distal Centralizer Sizes 1-11	Distal Centralizer Sizes 9-18	N/A

PERFORMANCE DATA

Endurance properties of the CoreHip cemented and uncemented (pressfit) stem, head and neck were evaluated in accordance to *Guidance for Industry and FDA Staff Non-clinical Information for Femoral Prostheses, September 17, 2007;* ASTM F2068-15; ISO 7206-4 and ISO 7206-6. Additional Femoral head/Taper testing was completed. Range of Motion (ROM) analysis to satisfy the requirements of ISO 21535 was completed. Testing demonstrated that the subject device is substantially equivalent to the Primary and reference predicate devices.

PYROGEN TESTING: LAL testing was completed and met the pyrogen limit of 20 E.U./device.

CONCLUSION: Based on the performance tests completed, AIS believes that CoreHip System is substantially equivalent to the Primary Predicate Excia® Total Hip System and Reference Predicate Fitmore Hip System.