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

January 19, 2017

Amplitude
Mireille Lemery
Director, Quality and Regulatory Affairs
11 Cours Jacques Offenbach
Valence, FR 26000
France

Re: K161414
Trade/Device Name: Anatomic Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: December 16, 2016
Received: December 19, 2016

Dear Mireille Lemery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161414

Device Name
ANATOMIC® Total Knee System

Indications for Use *(Describe)*
The ANATOMIC® Total Knee System is indicated for use in total knee arthroplasty as a result of:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis;
- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Revision of previous unsuccessful knee replacement or other procedure.

The ANATOMIC® Total Knee System is for single use only and is intended for implantation with bone cement only.

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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AMPLITUDE

510(k) Summary of Safety and Effectiveness Information

Traditional 510(k) Premarket - ANATOMIC® Total Knee System

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Date prepared: December 16th, 2016

Assigned 510(k) number:	K161414
Company:	AMPLITUDE 11, cours Jacques Offenbach, Zone Mozart 2 26000 Valence, FRANCE Phone: +33 4 75 81 34 95 Fax: +33 4 75 41 41 78
Contact:	Mireille LEMERY
Trade/Proprietary Name:	ANATOMIC® Total Knee System
Classification Name:	Knee Prosthesis
Classification/Product Code:	21 CFR 888.3560, Class II, Product Code JWH
Predicate Devices:	Scorpio® NRG® Knee, Howmedica Osteonics Corp, K030978, K042343, K071991 Freedom® Total Knee System, Maxx Orthopedics Inc, K082019, K090411

Service Client France
Porte du Grand Lyon
01700 Neyron - France
Tél : +33 (0)4 37 85 19 19
Fax : +33 (0)4 37 85 19 18

Export Customer Service
11, cours Jacques Offenbach
Zone Mozart 2
26000 Valence - France
Tél : +33 (0)4 75 41 87 41
Fax : +33 (0)4 75 41 87 42

E-mail :
amplitude@amplitude-ortho.com

Internet :
www.amplitude-ortho.com

1. Device Description

The ANATOMIC® Total Knee System belongs to the category of sliding posterior-stabilized total knee prostheses (PS, posterior-cruciate substituting).

The ANATOMIC® Total Knee System is intended for use as a semi-constrained replacement system. It consists of a femoral implant, a tibial implant and a patellar implant. The tibial implant consists of two components: tibial insert and tibial baseplate. The patellofemoral joint may be preserved or resurfaced with the patellar resurfacing implant.

The femoral implant comes in right and left versions and in various sizes. The tibial baseplate and tibial insert are symmetrical and can be used both for right and left sides. The tibial baseplate comes in various sizes. The tibial insert is available in various sizes and thicknesses.

The nominal size of the insert includes the thickness of the tibial baseplate. The standard keel (supplied in the tibial baseplate packaging) must be mounted and blocked on the implant by the surgeon before implantation.

The components are for cemented used only.

The selection of the appropriate implants can be made by using the recommendations of the surgical technique and by using the x-ray templates and trial implants supplied with the instrumentation.

2. Intended Use

The ANATOMIC® Total Knee System is intended for replacement of the knee joint to reduce pain and restore knee function in comparison with preoperative status.

3. Indications for use

The ANATOMIC® Total Knee System is indicated for use in total knee arthroplasty as a result of:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis;
- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Revision of previous unsuccessful knee replacement or other procedure.

The ANATOMIC® Total Knee System is for single use only and is intended for implantation with bone cement only.

4. Summary of technological characteristics

Table 1: Main features comparison

		ANATOMIC® Total Knee System	Scorpio® NRG® Knee	Freedom® Total Knee System	Substantial equivalence?
MATERIALS	Femoral implant	CoCr ISO 5832-4	CoCr ASTM F75	CoCr ASTM F75	YES
	Tibial baseplate	CoCr ISO 5832-4	CoCr ASTM F75	CoCr ASTM F75	YES
	Tibial insert	UHMW-PE ISO 5834-2	UHMW-PE ASTM F648	UHMW-PE ASTM F648	YES
	Patellar implant	UHMW-PE ISO 5834-2	UHMW-PE ASTM F648	UHMW-PE ASTM F648	YES
Employed technology		Posterior Stabilized	Posterior Stabilized	Posterior Stabilized	YES
Anchoring system		Cemented	Cemented	Cemented	YES

Service Client France
Porte du Grand Lyon
01700 Neyron - France
Tél : +33 (0)4 37 85 19 19
Fax : +33 (0)4 37 85 19 18

Export Customer Service
11, cours Jacques Offenbach
Zone Mozart 2
26000 Valence - France
Tél : +33 (0)4 75 41 87 41
Fax : +33 (0)4 75 41 87 42

E-mail :
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Internet :
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Intended Use	Total Knee Replacement	Total Knee Replacement	Total Knee Replacement	YES
Sterilization method	Gamma sterilization	Gamma sterilization	Gamma sterilization	YES
Maximum flexion	High flexion = 130° max	High flexion = 130° max	High flexion = 155° max	YES
Femoral component features				
Model	9 sizes	9 sizes	8 sizes	YES
Dimensions	AP from 49.83 to 72.86 mm ML 56 from to 76.7 mm	AP from 51 to 75 mm ML from 57 to 82 mm	AP from 51 to 74 mm ML 54 from to 78 mm	YES
Anchoring system	Cage's surfaces have negative macrostructure grooves type and cones with a depth of 0.5 mm as well as positive macrostructures pyramid type with a height of 0.5 mm The surface in contact with bone cement is shot-blasted	Wafle structures with a depth of 0.6 mm The surface in contact with bone cement is shot-blasted	Groove depth 0.8 mm The surface in contact with bone cement is shot-blasted	YES
Radius of curvature	Single radius of curvature from 0° to 100° flexion	Single radius of curvature from 0° to 95° flexion	Single radius of curvature from 15° to 120°	YES
Insert component features				
Model	9 sizes x 6 thickness	5 sizes x 7 thickness	8 sizes	YES
Thickness	Thickness: 10, 12, 14, 16, 18 and 20 mm with Tibial Tray Minimum Polyethylene Thickness: 6.8 without Tibial Tray	Thickness: 8, 10, 12, 15, 18, 21, 24 mm with Tibial Tray Minimum Polyethylene Thickness: 6 without Tibial Tray	N/K	YES
Insert minimum thickness (mm)	6.9 +/-0.1 mm	6 mm, tolerance unknown	N/K	YES
The anchoring system of the insert onto the tibial baseplate	Peripheral locks at six places (two anterior clips, posteromedial, posterolateral, lateral and medial dovetails)	- 2 posterior undercuts - 1 anterior wire Peripheral lip	Peripheral locks at five places (anterior, posteromedial, posterolateral, lateral and medial locking)	YES
Tibial component features				
Model	9 sizes	8 sizes	8 sizes	YES
Dimensions	AP from 39.09 to 57.31 mm	AP from 40 to 58 mm	AP from 40 to 54 mm	YES

Service Client France
Porte du Grand Lyon
01700 Neyron - France
Tél : +33 (0)4 37 85 19 19
Fax : +33 (0)4 37 85 19 18

Export Customer Service
11, cours Jacques Offenbach
Zone Mozart 2
26000 Valence - France
Tél : +33 (0)4 75 41 87 41
Fax : +33 (0)4 75 41 87 42

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	ML from 60 to 88 mm	ML from 61 to 88 mm	ML from 59 to 78 mm	
Tibial tray thickness (mm)	3 mm	2.5 mm	3.3 mm	YES
Stem length	41 mm	30 to 40 mm	N/K	YES
Surface aspect	Area in contact with bone cement: shot-blasted Surface in contact with tibial insert: mirror polished	Shot-blasted	Shot-blasted	YES
Patellar component features				
Model	4 diameters	6 models	4 diameters	YES
Dimension	30, 33, 36 and 39 mm	30, 32, 34, 36 and 38 mm	25, 28, 31 and 34 mm	YES
Thickness	8 mm	8 to 10 mm	Unknown	YES
Patella fixation	Resurfacing patella cemented with three pegs	Resurfacing patella are cemented with three pegs and grooves for cement.	All-poly resurfacing patella cemented with three pegs	YES
Patella shape	Spherical dome shape for resurfacing patella	Spherical dome shape for Universal Patella	Spherical dome shape for resurfacing patella	YES
Manufacturer	Amplitude	Howmedica Osteonics Corp.	Maxx Orthopedics, Inc.	-

The product subject of this premarket notification is substantially equivalent in design and functionality to the Scorpio® NRG® Knee (K030978) and Freedom® Total Knee System (K082019).

5. Non clinical testing

Functional testing was conducted in compliance with the FDA Guidance Class II/Special Controls Guidance Document Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA, issued January 16, 2003.

Specifically, the following non-clinical laboratory tests were performed to determine substantial equivalence:

- Tibial Baseplate fatigue test
- Insert (post) fatigue test
- Wear test
- Range of Motion
- Constraints Femoro-Tibial
- Constraints Patello-Femoral
- Contact Area/ Stress Femoro-Tibial
- Contact Area/ Stress Patello-Femoral
- Interlock Strength insert/ Baseplate

Service Client France
Porte du Grand Lyon
01700 Neyron - France
Tél : +33 (0)4 37 85 19 19
Fax : +33 (0)4 37 85 19 18

Export Customer Service
11, cours Jacques Offenbach
Zone Mozart 2
26000 Valence - France
Tél : +33 (0)4 75 41 87 41
Fax : +33 (0)4 75 41 87 42

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The UHMWPE material properties have been characterized according to test standards to demonstrate the conformity of the material.

The galvanic effect on the corrosion of the assembly between the tibial baseplate and the standard keel has been assessed according to relevant standard to demonstrate the conformity of the assembly.

MRI compatibility has not been evaluated for the ANATOMIC® Total Knee System.

The results of these tests demonstrate the equivalence between the ANATOMIC® Total Knee System and the Scorpio® NRG® Knee (K030978) and Freedom® Total Knee System (K082019).

6. Substantial Equivalence Conclusion

The proposed ANATOMIC® Total Knee System is believed to be substantially equivalent to the predicate devices with the same intended use and the same technological characteristics.

Service Client France
Porte du Grand Lyon
01700 Neyron - France
Tél : +33 (0)4 37 85 19 19
Fax : +33 (0)4 37 85 19 18

Export Customer Service
11, cours Jacques Offenbach
Zone Mozart 2
26000 Valence - France
Tél : +33 (0)4 75 41 87 41
Fax : +33 (0)4 75 41 87 42

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