DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 1, 2017

Zimmer Gmbh
Dr. Annemie Rehor Kausch
Senior Specialist Regulatory Affairs
Sulzerallee 8, P.O. Box
8404 Winterthur, Switzerland

Re: k170711
Trade/Device Name: ASHCOM™ Shoulder System, Anatomical Shoulder™ System And Anatomical Shoulder™ Combined System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, HSD, KWS, KWT, PAO
Dated: March 7, 2017
Received: March 8, 2017

Dear Dr. Kausch:

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,

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)*
K170711

Device Name
ASHCOM™ Shoulder System
Anatomical Shoulder™ System
Anatomical Shoulder™ Combined System

Indications for Use *(Describe)*
Anatomical Shoulder System and ASHCOM Shoulder System

Hemi or Total Arthroplasty Application of the Anatomical Shoulder Humeral Stems and Domelock System
The Anatomical Shoulder Humeral Stems and Domelock System are indicated for
• Advanced wear and tear of the shoulder joint resulting from degenerative, posttraumatic or rheumatoid arthritis.
• Avascular necrosis.
• Conditions consequent to earlier operations.
• Omarthrosis.
• Rheumatoid arthritis.
• Revision of shoulder prosthesis.

The Humeral Stems Cemented are intended for cemented use and the Humeral Stems Uncemented are intended for uncemented use. When used in a total shoulder application, the Anatomical Shoulder Pegged and Keeled Glenoids Cemented and the Biomet all-polyethylene Keeled Glenoid are intended for cemented use only. The Biomet Modular Hybrid Glenoid is intended to be implanted with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.

Reverse Application of the Anatomical Shoulder System and ASHCOM Shoulder System
• The Anatomical Shoulder Inverse/Reverse System and ASHCOM Shoulder System are indicated for primary, fracture or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.
• The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The Humeral Stems Cemented are intended for cemented use and the Humeral Stems Uncemented are intended for uncemented use. When used with the Anatomical Shoulder Glenoid Fixation, it is intended for uncemented use and requires two screws for fixation.

Fracture Application of the Anatomical Shoulder Fracture System
The Anatomical Shoulder Fracture System is intended for use in prosthetic replacement of the proximal humerus and the glenoid articular surface of the scapula during total-, hemi and fracture shoulder arthroplasty in treatment of the following:
• Complex 3- and 4-part fractures of the proximal humerus with subluxation of the head fragment
• Complex 3- and 4-part fractures of the proximal humerus with loosening of the spongiosa in the head fragment
• Complex 3- and 4-part fractures of the proximal humerus with additional cross split of the head fragment
• Fracture instability after osteosynthesis of 3- and 4-part fracture fragments of the proximal humerus
• Posttraumatic necrosis of the humeral head
• Posttraumatic arthrosis after humeral head fracture

The Humeral Fracture Stems are intended for either cemented or uncemented use. When used in a total shoulder application, the Anatomical Shoulder Pegged and Keeled Glenoids Cemented are intended for cemented use only.

Anatomical Shoulder Combined System
Advanced destruction of the shoulder joint resulting from:
• Omarthrosis.

• Rheumatoid arthritis
• Post-traumatic arthritis
• Avascular necrosis of the humeral head
• Cuff-tear arthropathy (Bigliani/Flatow Heads with heights of 27mm or greater)
• Conditions following earlier operations (including revision shoulder arthroplasty).
The Anatomical Shoulder Combined System is intended for cemented or cementless use.

When used with the following humeral stems the Anatomical Shoulder Combined System is intended for cemented use:
• Anatomical Shoulder Standard Cemented Humeral Stem.
• Anatomical Shoulder Revision Stem.

When used with the following humeral stem the Anatomical Shoulder Combined System is intended for cementless use:
• Anatomical Shoulder Standard Uncemented Stem.

When used with the following humeral stems the Anatomical Shoulder Combined System is intended for cemented or cementless use:
• Anatomical Shoulder Fracture Stem.
• Anatomical Shoulder Fracture Long Stem.

When used with the following glenoids the Anatomical Shoulder Combined System is intended for cemented use:
• Bigliani/Flatow Glenoid (pegged and keeled).
• Trabecular Metal™ Glenoid.

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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Zimmer GmbH
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8404 Winterthur
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510(k) Summary

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Annemie Rehor Kausch Senior Specialist, Regulatory Affairs Telephone: +41 58 854 82 61 Fax: + 41 52 244 86 58
Date:	May, 09, 2017
Trade Name:	ASHCOM ™ Shoulder System Anatomical Shoulder ™ System Anatomical Shoulder ™ Combined System
Classification Product Code /	**PHX** – Shoulder Prosthesis, Reverse Configuration **HSD** – Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented **KWS** – Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented **KWT** – Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented **PAO** - Prosthesis, Shoulder, Semi-constrained, Metal/Polymer + Additive, Cemented
Device Classification Name:	Shoulder Prosthesis
Regulation Number / Description:	21 CFR § 888.3690 – Shoulder joint humeral (hemishoulder) metallic uncemented prosthesis 21 CFR § 888.3660 – Shoulder joint metal/polymer semi-constrained cemented prosthesis 21 CFR § 888.3650 – Shoulder joint metal/polymer non-constrained cemented prosthesis
Predicate Device:	The following devices serve as predicate for the ASHCOM Shoulder System:

Anatomical Shoulder System manufactured by Zimmer GmbH, K142403, cleared November 24, 2014
Comprehensive Reverse Shoulder, manufactured by Biomet Inc, K080642, cleared September 7, 2008, K113069, cleared January 11, 2012 and K113121, cleared December 16, 2011.

The following predicate devices are labelled "MR conditional":

Anatomical Shoulder System, manufactured by Zimmer GmbH, K990136, cleared March, 01, 1999; K030259, cleared April, 24, 2003; K051623, cleared July, 19, 2005, K053274, January, 25, 2006; K052906, cleared December, 19, 2005; K062029, cleared October, 31, 2006; K142403 cleared November 24, 2014, K160085, cleared March, 8, 2016 and K161620, cleared November, 1, 2016.

Anatomical Shoulder Combined System, manufactured by Zimmer GmbH, K103404, cleared May, 15th, 2011.

Device Description:

The ASHCOM Shoulder AC-Connector is a double tapered Adaptor that allows the combination of the Anatomical Shoulder Humeral Stems with the Comprehensive Trays. The male oval cone taper of the ASHCOM Shoulder AC-Connector is compatible with the cemented, uncemented and fracture humeral stems of the Anatomical Shoulder System. The female round taper is compatible with the Comprehensive Reverse Trays. In combination with compatible Zimmer Biomet reverse glenoid the implant is intended for a reverse application.

The existing Anatomical Shoulder System, for which MR conditional labeling is proposed, is a modular shoulder prosthesis designed to be used in primary or revision, total or hemi shoulder arthroplasty.

The existing Anatomical Shoulder Combined System, for which MR conditional labeling is proposed, allows the combination of a Bigliani/Flatow® Head with any Anatomical Shoulder Humeral Stem.

Intended Use:

The Anatomical Shoulder System is intended for long-term implantation into the human shoulder joint in primary or revision, total or hemi shoulder arthroplasty. The system is intended to relieve pain and restore function in patients with adequate bone stock to support the prosthesis.

The ASHCOM Shoulder System is intended for reverse shoulder arthroplasty.

Indications for Use:

Hemi or Total Arthroplasty Application of the Anatomical Shoulder Humeral Stems and Domelock System

The Anatomical Shoulder Humeral Stems and Domelock System are indicated for

- Advanced wear and tear of the shoulder joint resulting from degenerative, posttraumatic or rheumatoid arthritis.
- Avascular necrosis.
- Conditions consequent to earlier operations.
- Omarthrosis.
- Rheumatoid arthritis.
- Revision of shoulder prosthesis.

The Humeral Stems Cemented are intended for cemented use and the Humeral Stems Uncemented are intended for uncemented use. When used in a total shoulder application, the Anatomical Shoulder Pegged and Keeled Glenoids Cemented and the Biomet all-polyethylene Keeled Glenoid are intended for cemented use only. The Biomet Modular Hybrid Glenoid is intended to be implanted with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.

Reverse Application of the Anatomical Shoulder System and ASHCOM Shoulder System

- The Anatomical Shoulder Inverse/Reverse System and the ASHCOM Shoulder System are indicated for primary, fracture or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.
- The patient's joint must be anatomically and structurally suited to receive the selected implants and

a functional deltoid muscle is necessary to use the device.

The Humeral Stems Cemented are intended for cemented use and the Humeral Stems Uncemented are intended for uncemented use. When used with the Anatomical Shoulder Glenoid Fixation, it is intended for uncemented use and requires two screws for fixation.

Fracture Application of the Anatomical Shoulder Fracture System

The Anatomical Shoulder Fracture System is intended for use in prosthetic replacement of the proximal humerus and the glenoid articular surface of the scapula during total-, hemi and fracture shoulder arthroplasty in treatment of the following:
• Complex 3- and 4-part fractures of the proximal humerus with subluxation of the head fragment
• Complex 3- and 4-part fractures of the proximal humerus with loosening of the spongiosa in the head fragment
• Complex 3- and 4-part fractures of the proximal humerus with additional cross split of the head fragment
• Fracture instability after osteosynthesis of 3- and 4-part fracture fragments of the proximal humerus
• Posttraumatic necrosis of the humeral head
• Posttraumatic arthrosis after humeral head fracture

The Humeral Fracture Stems are intended for either cemented or uncemented use. When used in a total shoulder application, the Anatomical Shoulder Pegged and Keeled Glenoids Cemented are intended for cemented use only.

Anatomical Shoulder Combined System
Advanced destruction of the shoulder joint resulting from:
• Omarthrosis.
• Rheumatoid arthritis
• Post-traumatic arthritis
• Avascular necrosis of the humeral head
• Cuff-tear arthropathy (Bigliani/Flatow Heads with heights of 27mm or greater)

• Conditions following earlier operations (including revision shoulder arthroplasty).

The Anatomical Shoulder Combined System is intended for cemented or cementless use.

When used with the following humeral stems the Anatomical Shoulder Combined System is intended for cemented use:
• Anatomical Shoulder Standard Cemented Humeral Stem.
• Anatomical Shoulder Revision Stem.

When used with the following humeral stem the Anatomical Shoulder Combined System is intended for cementless use:
• Anatomical Shoulder Standard Uncemented Stem.

When used with the following humeral stems the Anatomical Shoulder Combined System is intended for cemented or cementless use:
• Anatomical Shoulder Fracture Stem.
• Anatomical Shoulder Fracture Long Stem.

When used with the following glenoids the Anatomical Shoulder Combined System is intended for cemented use:
• Bigliani/Flatow Glenoid (pegged and keeled).
• Trabecular Metal™ Glenoid.

Comparison to Predicate Device:

The ASHCOM AC-Connector allows the combination of the Anatomical Shoulder Humeral Stems with the Comprehensive Reverse Trays. The indications are shared with the reverse application of the Anatomical Shoulder predicate device. The ASHCOM AC-Connector utilizes the same material as the Anatomical Shoulder Humeral Stem and the same manufacturing process, and has similar technical features as the Anatomical Shoulder predicate device.

This submission further covers a labeling modification to the existing Anatomical Shoulder and Anatomical Shoulder Combined System. The labeling modification consists of the addition of Magnetic Resonance Imaging (MRI) compatibility information to the Package Insert, and application of the “MR

	Conditional" symbol on the package label. No other changes are proposed.
Performance Data (Nonclinical and/or Clinical):	Results of non-clinical performance testing and analyses demonstrate that the ASHCOM Shoulder System is safe and effective and substantially equivalent to the predicate devices. Performance analyses included: 1. Finite Element Stress analysis and cyclic fatigue testing under worst case conditions 2. Accelerated Corrosion Fatigue Testing 3. Static taper connection testing according ASTM F2009 The components of the ASHCOM Shoulder System, the Anatomical Shoulder System and the Anatomical Shoulder Combined System and have been evaluated for compatibility in the MRI environment, per Guidance for Industry and FDA Staff, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", August 2014. Based upon the results, the subject shoulder implants are recommended to bear the "MR Conditional" labeling and include MR compatibility safety information within the package insert. Clinical Performance and Conclusions: Clinical data and conclusions were not needed to demonstrate substantial equivalence.