LimaCorporate S.p.A.
℅ Lacey Harbour
US Regulatory Manager
Lima USA Inc.
2001 NE Green Oaks Blvd. Ste.100
Arlington, Texas 76006

February 25, 2022

Re: K212800
Trade/Device Name: PRIMA Humeral System and SMR Glenosphere Ø42
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT, HSD, PAO
Dated: January 21, 2022
Received: January 25, 2022

Dear Lacey Harbour:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Lixin Liu, Ph.D.
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K212800

Device Name
PRIMA Humeral System and SMR Glenosphere Ø42

Indications for Use *(Describe)*

## PRIMA Humeral System

The PRIMA humeral system is intended for partial or total, primary or revision, shoulder joint replacement in skeletally mature patients. 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 PRIMA Stem is intended for use in cementless and cemented applications, at the discretion of the surgeon.

The PRIMA Anatomic implant is indicated for partial or total, primary or revision shoulder joint replacement, in patients suffering from pain and disability due to:

- Non-inflammatory degenerative joint disease (i.e. osteoarthritis),
- Inflammatory arthritis of the glenohumeral join including rheumatoid arthritis,
- Avascular necrosis of the humeral head,
- Traumatic/post-traumatic arthritis,
- Fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains,
- Post-fracture deformity with intact rotator cuff, where adequate fixation can be achieved and adequate bone stock remains,
- Cuff tear arthropathy (CTA Heads only).

The PRIMA Reverse implant is indicated for primary reverse total shoulder replacement or for revision when converting an anatomic PRIMA arthroplasty to a reverse total shoulder arthroplasty (i.e. in case of cuff tear arthropathy or in a grossly rotator cuff deficiency joint with severe arthropathy).
Revision surgery with retention of the PRIMA Stem is intended as conversion surgery from anatomic to reverse, where the PRIMA Stem is stable, well positioned and tissue integrated. Other revisions of the humeral prosthesis part should be treated with traditional shoulder prostheses.

The PRIMA reverse implant is indicated for patients suffering from pain and disability due to:

- Rotator cuff tear arthropathy,
- Osteoarthritis with rotator cuff tear,
- Rheumatoid arthritis with rotator cuff tear,
- Massive irreparable rotator cuff tear,
- Avascular necrosis of the humeral head,
- Correction of functional deformity, where adequate fixation can be achieved and adequate bone stock remains,
- Fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains.

The PRIMA Humeral System consists of the following single use components:

- Anatomic configuration:
  - stem
  - adaptor for humeral heads.
- Reverse configuration:
  - stem
  - reverse tray and
  - reverse insert.

The PRIMA Humeral System is intended to be used with all SMR glenoids implants.

**SMR Glenosphere Ø42**

The SMR Shoulder System is intended for partial or total, primary or revision shoulder joint replacement. The SMR Anatomic Shoulder System is indicated for partial or total, primary or revision shoulder joint replacement in patients suffering from disability due to:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- inflammatory degenerative joint disease such as rheumatoid arthritis;
- treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- revision of a failed primary implant; in case of SMR Short Stems only if sufficient bone stock remains);
- cuff tear arthropathy (CTA Heads only);
- glenoid arthrosis without excessive glenoid bone loss: A1, A2 and B1 according to Walch classification (SMR TT Hybrid Glenoid only).

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabled shoulder). 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 SMR TT Hybrid Glenoid Reverse Baseplate must not be used in cases of excessive glenoid bone loss and/or when bone graft is needed.

The Modular SMR Shoulder System allows the assembly of components in various humeral and glenoid constructs. The constructs are intended for cemented and uncemented use as specified in the following table.

In the Anatomic shoulder the humeral construct consists of the humeral stem, the humeral body, the adaptor taper and the humeral head. In the Reverse shoulder the humeral construct consists of the humeral stem, the reverse humeral body and the reverse liner. On the humeral side the fixation of the humeral stem determines if the construct is cemented or uncemented.
The Anatomic glenoid construct consists of an all polyethylene glenoid, a polyethylene glenoid with metal peg or a metal back assembled with a liner; the Reverse glenoid consists of a metal back/connector/glenosphere construct or of a peg/baseplate/glenosphere construct.
On the glenoid side, the fixation of the all polyethylene glenoid, the polyethylene glenoid with metal peg or the metal back determines if the construct is cemented or uncemented.

| System | | Components | Material | System use | |
|---|---|---|---|---|---|
| A | R | | | Cem | Not Cem |
| • | • | SMR Stems (Cemented, Cemented Revision) | Ti6Al4V | X | |
| • | • | SMR Stems (Cementless Finned, Cementless Revision) | Ti6Al4V | | X |
| • | • | SMR Short Stems (Cementless Finned) | Ti6Al4V | | X |
| • | | SMR Humeral Bodies (Trauma, Finned) | Ti6Al4V | X | X |
| • | • | SMR Reverse Humeral Body | Ti6Al4V | X | X |
| • | • | Humeral Extension | Ti6Al4V | X | X |
| • | | SMR Humeral Heads (Standard*, CTA) | CoCrMo | X | X |
| • | | SMR Adaptor Tapers (Neutral, Eccentric) | Ti6Al4V | X | X |
| • | | SMR CTA Head Adaptor for Reverse Humeral Body | Ti6Al4V | X | X |
| | • | SMR Glenospheres* | CoCrMo | | X |
| | • | SMR Connectors* | Ti6Al4V | | X |
| | • | Reverse Liners | UHMWPE | X | X |
| • | | SMR Cemented Glenoids | UHMWPE | X | |
| • | | SMR 3 Pegs Cemented Glenoids | UHMWPE | X | |
| • | • * | SMR TT Hybrid Glenoid | UHMWPE+Ti6Al4V+Ta | X | X |
| | • | SMR TT Hybrid Glenoid Reverse Baseplate + Screw | Ti6Al4V | | X |
| • | • | SMR Metal Back Glenoids | Ti6Al4V+PoroTi | X* | X* |
| • | • | SMR TT Baseplate | Ti6Al4V | X* | X* |
| | • | SMR TT Augmented 360 Baseplate | Ti6Al4V | | X |
| • | • | SMR TT Glenoid Peg | Ti6Al4V | X | X |
| • | | SMR Metal Back Liner | UHMWPE | X* | X* |
| • * | • | SMR Bone screws | Ti6Al4V | | X |

**Material Standards**

**Ti6Al4V** (ISO 5832-3 - ASTM F1472) - **CoCrMo** (ISO 5832-12 - ASTM F1537) – **UHMWPE** (ISO 5834-2 - ASTM F648) - **PoroTi Titanium Coating** (ASTM F1580) - **Ta** (ISO13782 - ASTM F560)

**A= Anatomic / R=Reverse**

***NOTE:**

- **When considering the humeral side, SMR Glenosphere Ø42 can be coupled only with PRIMA Humeral System.**

- **In the US, the SMR Metal Backed Glenoid/Liner construct, used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws.**
- **The SMR Metal Backed Glenoid/Connector/Glenosphere construct, used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.**
- **SMR Lateralized Connectors are not indicated for use with glenoid bone grafting techniques.**
- **In the US the SMR TT Metal Back Baseplate used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws; while when used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.**
- **If a SMR TT Hybrid Glenoid is in place and revision to a reverse prosthesis is required, the patient can be revised by removing the polyethylene baseplate, leaving the metal peg in place and by connecting it to the SMR TT Hybrid Glenoid Reverse Baseplate. The SMR TT Hybrid Glenoid Reverse Baseplate is intended for uncemented use with the addition of screws for fixation.**
- **The Dia. 50, 52 and 54mm Humeral Heads with + 3mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric). The Dia. 52 and 54mm Humeral Heads with + 2mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric).**

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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# 510(k) Summary

Date: August 25th, 2021

Manufacturer:
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| Product | Product Code | Regulation and Classification Name |
|---|---|---|
| **PRIMA Humeral System** | HSD | Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented per 21 CFR 888.3690 |
| | PAO | Shoulder joint metal/polymer semi-constrained cemented prosthesis, per 21 CFR 888.3660 |
| | PHX | Shoulder Prosthesis, Reverse Configuration per 21 CFR 888.3660 |
| | KWS | Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented per 21 CFR 888.3660 |
| | KWT | Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented per 21 CFR 888.3650 |
| **SMR Glenosphere Ø42** | HSD | Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented per 21 CFR 888.3690 |
| | PHX | Shoulder Prosthesis, Reverse Configuration per 21 CFR 888.3660 |
| | KWS | Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented per 21 CFR 888.3660 |
| | KWT | Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented per 21 CFR 888.3650 |

## Name of the Device

The PRIMA Humeral System is the subject of this 510(k) and includes the SMR Glenosphere Ø42.

| Product | Name of the device | Common or usual name of the device |
|---|---|---|
| **PRIMA Humeral System** | PRIMA Humeral System | Humeral shoulder prosthesis |
| **SMR Glenosphere Ø42** | SMR Glenosphere Ø42 | Glenoid shoulder prosthesis |

**Description:**

The PRIMA Humeral System is the subject of this 510(k) and includes the SMR Glenosphere Ø42.

The PRIMA Stem is a convertible short stem component with proximal fixation with Trabecular Titanium to be used in both anatomic and reverse configurations. Depending on the configuration, the short stem component (Ti6Al4V) can be coupled with an Adaptor for the humeral heads (Ti6Al4V) in case on anatomic system and with a Reverse Tray (Ti6Al4V) and Reverse Insert (LimaVit E UHMWPE Ti6Al4V ring) only in case of reverse. The PRIMA Stem is intended for use in cementless and cemented applications, at the discretion of the surgeon.

When used in reverse configuration, the PRIMA Stem is coupled with a Glenosphere through a Reverse Tray and a Reverse Insert. PRIMA Stem is compatible with already cleared SMR Glenospheres Ø36 and Ø40 (K110598, K142139, K163397). In addition, PRIMA Stem is compatible with the new SMR Glenosphere Ø42 (CoCrMo), subject of the present 510(k).

**Indications for Use:**

**PRIMA Humeral System**

The PRIMA humeral system is intended for partial or total, primary or revision, shoulder joint replacement in skeletally mature patients. 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 PRIMA Stem is intended for use in cementless and cemented applications, at the discretion of the surgeon.

The PRIMA Anatomic implant is indicated for partial or total, primary or revision shoulder joint replacement, in patients suffering from pain and disability due to:

- Non-inflammatory degenerative joint disease (i.e. osteoarthritis),
- Inflammatory arthritis of the glenohumeral join including rheumatoid arthritis,
- Avascular necrosis of the humeral head,
- Traumatic/post-traumatic arthritis,
- Fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains,

- Post-fracture deformity with intact rotator cuff, where adequate fixation can be achieved and adequate bone stock remains,
- Cuff tear arthropathy (CTA Heads only).

The PRIMA Reverse implant is indicated for primary reverse total shoulder replacement or for revision when converting an anatomic PRIMA arthroplasty to a reverse total shoulder arthroplasty (i.e., in case of cuff tear arthropathy or in a grossly rotator cuff deficiency joint with severe arthropathy).
Revision surgery with retention of the PRIMA Stem is intended as conversion surgery from anatomic to reverse, where the PRIMA Stem is stable, well positioned and tissue integrated. Other revisions of the humeral prosthesis part should be treated with traditional shoulder prostheses.

The PRIMA reverse implant is indicated for patients suffering from pain and disability due to:

- Rotator cuff tear arthropathy,
- Osteoarthritis with rotator cuff tear,
- Rheumatoid arthritis with rotator cuff tear,
- Massive irreparable rotator cuff tear,
- Avascular necrosis of the humeral head,
- Correction of functional deformity, where adequate fixation can be achieved and adequate bone stock remains,
- Fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains.

The PRIMA Humeral System consists of the following single use components:

- Anatomic configuration:
  - stem
  - adaptor for humeral heads.
- Reverse configuration:
  - stem
  - reverse tray and
  - reverse insert.

The PRIMA Humeral System is intended to be used with all SMR glenoid implants.

**SMR Glenosphere Ø42**
The SMR Shoulder System is intended for partial or total, primary or revision shoulder joint replacement.
The SMR Anatomic Shoulder System is indicated for partial or total, primary or revision shoulder joint replacement in patients suffering from disability due to:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- inflammatory degenerative joint disease such as rheumatoid arthritis;

- treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- revision of a failed primary implant; in case of SMR Short Stems only if sufficient bone stock remains);
- cuff tear arthropathy (CTA Heads only);
- glenoid arthrosis without excessive glenoid bone loss: A1, A2 and B1 according to Walch classification (SMR TT Hybrid Glenoid only).

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabled shoulder). 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 SMR TT Hybrid Glenoid Reverse Baseplate must not be used in cases of excessive glenoid bone loss and/or when bone graft is needed.

The Modular SMR Shoulder System allows the assembly of components in various humeral and glenoid constructs. The constructs are intended for cemented and uncemented use as specified in the following table.

In the Anatomic shoulder the humeral construct consists of the humeral stem, the humeral body, the adaptor taper and the humeral head. In the Reverse shoulder the humeral construct consists of the humeral stem, the reverse humeral body and the reverse liner. On the humeral side the fixation of the humeral stem determines if the construct is cemented or uncemented.
The Anatomic glenoid construct consists of an all polyethylene glenoid, a polyethylene glenoid with metal peg or a metal back assembled with a liner; the Reverse glenoid consists of a metal back/connector/glenosphere construct or of a peg/baseplate/glenosphere construct.
On the glenoid side, the fixation of the all polyethylene glenoid, the polyethylene glenoid with metal peg or the metal back determines if the construct is cemented or uncemented.

| System | | Components | Material | System use | |
|---|---|---|---|---|---|
| A | R | | | Cem | Not Cem |
| • | • | SMR Stems (Cemented, Cemented Revision) | Ti6Al4V | X | |
| • | • | SMR Stems (Cementless Finned, Cementless Revision) | Ti6Al4V | | X |
| • | • | SMR Short Stems (Cementless Finned) | Ti6Al4V | | X |
| • | | SMR Humeral Bodies (Trauma, Finned) | Ti6Al4V | X | X |
| • | • | SMR Reverse Humeral Body | Ti6Al4V | X | X |
| • | • | Humeral Extension | Ti6Al4V | X | X |
| • | | SMR Humeral Heads (Standard*, CTA) | CoCrMo | X | X |
| • | | SMR Adaptor Tapers (Neutral, Eccentric) | Ti6Al4V | X | X |
| • | | SMR CTA Head Adaptor for Reverse Humeral Body | Ti6Al4V | X | X |
| | • | SMR Glenospheres* | CoCrMo | | X |
| | • | SMR Connectors* | Ti6Al4V | | X |

| System | | Components | Material | System use | |
|---|---|---|---|---|---|
| A | R | | | Cem | Not Cem |
| | ● | Reverse Liners | UHMWPE | X | X |
| ● | | SMR Cemented Glenoids | UHMWPE | X | |
| ● | | SMR 3 Pegs Cemented Glenoids | UHMWPE | X | |
| ● | ● * | SMR TT Hybrid Glenoid | UHMWPE+Ti6Al4V+Ta | X | X |
| | ● | SMR TT Hybrid Glenoid Reverse Baseplate + Screw | Ti6Al4V | | X |
| ● | ● | SMR Metal Back Glenoids | Ti6Al4V+PoroTi | X* | X* |
| ● | ● | SMR TT Baseplate | Ti6Al4V | X* | X* |
| | ● | SMR TT Augmented 360 Baseplate | Ti6Al4V | | X |
| ● | ● | SMR TT Glenoid Peg | Ti6Al4V | X | X |
| ● | | SMR Metal Back Liner | UHMWPE | X* | X* |
| ● * | ● | SMR Bone screws | Ti6Al4V | | X |
| **Material Standards** | | | | | |
| **Ti6Al4V** (ISO 5832-3 - ASTM F1472) - **CoCrMo** (ISO 5832-12 - ASTM F1537) – **UHMWPE** (ISO 5834-2 - ASTM F648) - **PoroTi Titanium Coating** (ASTM F1580) - **Ta** (ISO13782 - ASTM F560) | | | | | |

**A= Anatomic / R=Reverse**

***NOTE:**

- **When considering the humeral side, SMR Glenosphere Ø42 can be coupled only with PRIMA Humeral System.**
- **In the US, the SMR Metal Backed Glenoid/Liner construct, used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws.**
- **The SMR Metal Backed Glenoid/Connector/Glenosphere construct, used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.**
- **SMR Lateralized Connectors are not indicated for use with glenoid bone grafting techniques.**
- **In the US the SMR TT Metal Back Baseplate used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws; while when used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.**
- **If a SMR TT Hybrid Glenoid is in place and revision to a reverse prosthesis is required, the patient can be revised by removing the polyethylene baseplate, leaving the metal peg in place and by connecting it to the SMR TT Hybrid Glenoid Reverse Baseplate. The SMR TT Hybrid Glenoid Reverse Baseplate is intended for uncemented use with the addition of screws for fixation.**
- **The Dia. 50, 52 and 54mm Humeral Heads with + 3mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric). The Dia. 52 and 54mm Humeral Heads with + 2mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric).**

**Predicate Devices:**
The PRIMA Humeral System is substantially equivalent in materials, indications, function and/or performance to the following predicate devices:

| Product | Primary predicate devices | Additional predicate devices |
|---|---|---|
| **PRIMA Humeral System** | DJO:<br>AltiVate Reverse Humeral Stem (K190290) | • DJO, AltiVate Anatomic™ Shoulder System (K162024)<br>• DJO, AltiVate Reverse Humeral Stem, AltiVate Reverse Small Spacer, Altivate Reverse, Small Hemi-Adapter, AltiVate Reverse, Small Socket Insert (K172351),<br>• DJO, AltiVate Anatomic to Reverse Conversion Module (K173073)<br>• TORNIER, Aequalis Ascend Flex (K122698)<br>• TORNIER, PERFORM Humeral System – Stem (K201315) |

The following predicate devices were chosen for the subject **SMR Glenosphere Ø42**:

| Product | Primary predicate devices | Other predicate devices |
|---|---|---|
| **SMR Glenosphere Ø42** | LimaCorporate Spa, SMR Reverse Shoulder System (K110598) | TORNIER, Aequalis Ascend Flex (K122698) |

**Summary of technology comparison:**
**PRIMA Humeral System** is substantially equivalent to the predicate devices identified.
The PRIMA Stem has many design features similar to the predicates, as the minimal lateral length, the humeral neck angle, the option to couple with the other components, antirotational stability solutions, and the porous coating. The porous coating is a Trabecular Titanium external structure, which is the same Trabecular Titanium structure of the device previously cleared via K133349.
All devices are made of the same metal material.
The Reverse Insert has same design of the PERFORM Humeral System (K201315), and the other predicates have similar features. The subject device is made of Vit E poly as the predicates K162024, K172351, K173073, K190290 and of metal as the predicate K122698. The Reverse Insert has more diameters as the predicate devices K162024, K172351, K173073, K190290 and has more thicknesses as the predicate K122698.

The reverse tray has the same features of the basic ones of the PERFORM Humeral System , is made of the same material, but has more sizes as the PERFORM Humeral System. The adaptor has a double male taper and an eccentricity as the PERFORM Humeral System; both are made of titanium and have different sizes and offsets.
All components are provided sterile. The methods used for the subject devices are commonly used in orthopedic prosthesis and are the same used for the predicates K162024, K172351, K173073, K190290: rays for metal components, EtO for poly components.

**SMR Glenosphere Ø42** has identical technological characteristics and design of K110598, except for the new diameter size, that is the same of the Tornier Glehosphere (K081016).

The predicates and the **PRIMA Humeral System** have substantially equivalent intended uses and indications for use. In details, all indications for use of **PRIMA Humeral System** are the same provided for the DJO Altivate predicate. The TORNIER Aequalis Ascend Flex has the most of indication for use provided for the subject devices, except only for the "avascular necrosis of the humeral head" and for the "Cuff tear arthropathy" in anatomic configuration, and for the "Rotator cuff tear arthropathy" in reverse configuration. The TORNIER PERFORM Humeral System has similar indication for use then the subject devices, with few exceptions.

The indications for use for the subject **SMR 42mm Glenosphere** are identical to the indications for use of predicate device, K110598 the Limacorporate SMR Reverse Shoulder System; both the subject device and predicate K110598 are intended to be used for reverse shoulder replacement using components of the SMR Reverse Shoulder System according to the indications for use described for the SMR Reverse Shoulder System cleared via K110598. The indications for use of the subject device are also like those of the other cited predicate.
All subject and predicate devices have the same stem fixation.

**Non-clinical testing**
The following tests are performed in support of the PRIMA Humeral System and SMR Glenosphere Ø42 performance:

- Fretting Fatigue in anatomic and reverse configuration;
- Fatigue test on polyethylene liner;
- Dynamic Evaluation of the Glenoid Loosening or Disassociation (ASTM F2028);
- Coupling resistance under static load: push-out, lever-out and torque-out tests;
- Wear test, as per ISO 14242 – 2 and ASTM F2003;
- Biocompatibility evaluation, as per ISO 10993-1;
- Endotoxin assessment, as per ANSI/AAMI ST72;
- Packaging and shelf life validation as per ISO 11607-1/-2;
- Sterilization validation, as per ISO 11137-1/-2/-3.

**Clinical testing**

Clinical testing was not necessary to demonstrate substantial equivalence of **PRIMA Humeral System** and **SMR Glenosphere Ø42.**

**Conclusion**

Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, PRIMA Humeral System and SMR Glenosphere Ø42 are substantially equivalent to the respective predicate devices identified in this premarket notification.