Implantcast GmbH
Dave McGurl
Director, Regulatory Affairs
Mrca, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001
USA

November 13, 2020

Re: Re: K191433
Trade/Device Name: AGILON® XO Shoulder Replacement System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSD, PHX
Dated: November 9, 2020
Received: November 9, 2020

Dear Dave McGurl:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 12, 2020. Specifically, FDA is updating the SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Michael Owens, OHT6: Office of Orthopedic Devices, 301-796-5650, Michaelc.Owens@fda.hhs.gov.

Sincerely,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2020.11.13 13:19:49 -05'00'

For Michael Owens
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

Implantcast GmbH
Dave McGurl
Director, Regulatory Affairs MRCA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001
USA

November 12, 2020

Re: K191433
Trade/Device Name: AGILON® XO Shoulder Replacement System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD, PHX, MBF
Dated: November 9, 2020
Received: November 9, 2020

Dear Dave McGurl:

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2020.11.12 17:59:26 -05'00'

For Michael Owens
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)*
K191433

Device Name
AGILON® XO Shoulder Replacement System

Indications for Use *(Describe)*

The AGILON® XO Shoulder Replacement System is indicated for use for cementless inverse (reverse) total or hemi shoulder replacement in cases of:

- Non- inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- Post-traumatic osteoarthritis,
- Fractures,
- Rheumatoid arthritis.

The main indications for the implantation of an AGILON® hemi shoulder prosthesis are:

- Multifragmental comminuted fractures of the humeral head,
- 3- and 4-Fragment-fractures of the proximal humerus,
- Head-splitting fractures,
- Dislocated head-splitting fractures,
- Humeral head depression with more than 40% of joint surface depressed,
- Interlocking chronic dislocation with deep HILL-SACHS lesion,
- Fracture instability following internal fixation attempt in 3-fragment and 4-fragment fractures (secondary dislocation, material loosening),
- Posttraumatic humeral head necrosis,
- Omarthrosis.

AGILON® CTA heads are destined for treatment of stable types of rotator cuff tear arthropathy. In order to achieve satisfactory results with the CTA heads the fornix humeri and the subscapularis tendon must be intact. A CTA cap is intended for the use as a hemi-arthroplasty, to treat a patient after an inverse shoulder has failed. It is not combined with a glenoid implant. It can be used in primary and revision cases.

The main indications for the implantation of an AGILON® inverse (reverse) shoulder prosthesis are:

- Rotator cuff tear arthropathy,
- Chronic trauma shoulder,
- Decentering of the humeral head after implantation of a humeral head prosthesis.

Please note, that the patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary.

In case of revision surgery the available bone stock has to be evaluated to allow for implantation of well-fixed stems. Conversion of the system can be performed in revision cases as follows:

- From Hemi Shoulder Arthroplasty to Hemi CTA Shoulder Arthroplasty
- From Hemi Shoulder Arthroplasty to Inverse (Reverse) Total Shoulder Arthroplasty
- From Inverse (Reverse) Total Shoulder Arthroplasty to Hemi Shoulder Arthroplasty as salvage procedure
- From Inverse (Reverse) Total Shoulder Arthroplasty to Hemi CTA Shoulder Arthroplasty as salvage procedure

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The surgeon decides which version of prosthesis for the individual patient is used. This decision depends on several factors, such as the age and the patient's weight, bone quality, shape of the bone and deformation of the joint.

The provision of prostheses is generally indicated only in patients whose skeleton is fully grown.

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

**Device Trade Name:** AGILON® XO Shoulder Replacement System

**Manufacturer:**
implantcast, GmbH
Lüneburger Schanze 26
21614 Buxtehude, Germany

**Contact:**
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**Prepared by:**
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1050 K Street NW, Suite 1000
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Phone: 202.552.5800
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**Date Prepared:** November 12, 2020

**Classification:**
21 CFR 888.3660, Shoulder joint metal/polymer semi-constrained cemented prosthesis

21 CFR 888.3690, Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis

**Class:** II

**Product Code:** HSD, PHX

**Primary Predicate Device:** DePuy Global UNITE Shoulder System (K170748)

**Additional Predicates:**
Stryker ReUnion Systems (K183039)
Medacta Shoulder System (K170910, K170452)
Delta CTA Reverse Shoulder System Humeral Heads (K062116)

**Indications for Use:**
The AGILON® XO Shoulder Replacement System is indicated for use for cementless inverse (reverse) total or hemi shoulder replacement in cases of:

- Non- inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,

- Post-traumatic osteoarthritis,
- Fractures,
- Rheumatoid arthritis.

The main indications for the implantation of an AGILON® hemi shoulder prosthesis are:

- Multifragmental comminuted fractures of the humeral head,
- 3- and 4-Fragment-fractures of the proximal humerus,
- Head-splitting fractures,
- Dislocated head-splitting fractures,
- Humeral head depression with more than 40% of joint surface depressed,
- Interlocking chronic dislocation with deep HILL-SACHS lesion,
- Fracture instability following internal fixation attempt in 3-fragment and 4-fragment fractures (secondary dislocation, material loosening),
- Posttraumatic humeral head necrosis,
- Omarthrosis.

AGILON® CTA heads are destined for treatment of stable types of rotator cuff tear arthropathy. In order to achieve satisfactory results with the CTA heads the fornix humeri and the subscapularis tendon must be intact. A CTA cap is intended for the use as a hemi-arthroplasty, to treat a patient after an inverse shoulder has failed. It is not combined with a glenoid implant. It can be used in primary and revision cases.

The main indications for the implantation of an AGILON® inverse (reverse) shoulder prosthesis are:

- Rotator cuff tear arthropathy,
- Chronic trauma shoulder,
- Decentering of the humeral head after implantation of a humeral head prosthesis.

Please note, that the patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary.

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- From Inverse (Reverse) Total Shoulder Arthroplasty to Hemi Shoulder Arthroplasty as salvage procedure
- From Inverse (Reverse) Total Shoulder Arthroplasty to Hemi CTA Shoulder Arthroplasty as salvage procedure

The surgeon decides which version of prosthesis for the individual patient is used. This decision depends on several factors, such as the age and the patient's weight, bone quality, shape of the bone and deformation of the joint.

The provision of prostheses is generally indicated only in patients whose skeleton is fully grown.

**Device Description:**
The AGILON® XO Shoulder Replacement System is a modular shoulder replacement system offering various components that can be combined to replace the shoulder joint with various options depending upon the size and of each patient. The components can be combined into an hemi or reverse shoulder:

**Hemi Shoulder:**
- Humeral Head Components (AGILON® XO Cap and AGILON® XO CTA Cap)
- Humeral Stems (Cementless)

**Reverse Shoulder:**
- Humeral Head Components (AGILON® Cap Inverse and AGILON® PE-Inlay)
- Glenoid and Glenosphere Components (AGLION® XO Glenoid Baseplate and AGILON® Glenosphere)
- Humeral Stems (Cementless)

Metaphyseal components, stem extension pieces, and component connection fixation screws are intended to be used for hemi and reverse shoulder configurations.

**Substantial Equivalence:**
The AGILON® XO Shoulder Replacement System is substantially equivalent to the predicate devices cited on the previous page with respect to intended use, design, and materials.

**Performance Testing:**
All necessary testing has been performed for the worst-case configuration of the AGILON® XO Shoulder Replacement System to assure substantial equivalence to its predicates and to demonstrate the subject devices perform as intended. All testing was performed on test units representative of finished devices. The performance of the AGILON® XO Shoulder Replacement System was characterized through the following tests:

- Testing of Metallic Medical Bone Screws (ASTM F543)
    - Torsional characterization, driving torque, and pull-out strength testing
- Glenoid Loosening or Disassociation (ASTM 2028)
    - Subluxation and cyclic testing
- Disassembly Testing (ASTM F1820)
    - Axial disassembly, offset pull-out, and torque out disassembly testing
- Axial Disassembly of Taper Connections (ASTM F2009)
    - Metaphyseal loosening
- Fatigue, fretting, corrosion, and metal ion analysis testing
- Microstructural Analysis
- Range of motion evaluation
- Biocompatibility Testing and Risk Assessment

**Conclusion:**
The AGILON® XO Shoulder Replacement System possesses the same intended use and technological characteristics as the predicate devices. Therefore, the AGILON® XO Shoulder Replacement System is substantially equivalent for its intended use.