510(K) SUMMARY

Manufacturer:	implantcast GmbH Lüneburger Schanze 26 21614 Buxtehude Germany
Contact:	Ms. Juliane Höppner Head of Regulatory Affairs implantcast GmbH Lüneburger Schanze 26 21614 Buxtehude Germany Phone: +49 4161 744 135 Fax: +49 4161 744 200 Email: j.hoeppner@implantcast.de
Prepared By:	Mr. Dave McGurl MCRA, LLC 803 7th Street NW, Floor 3 Washington, DC 20001 Phone: 202.552.5797 dmcgurl@mcra.com
Date Prepared:	August 17, 2022
Device Trade Name:	AGILON XO Shoulder System
Device Class and Common Name:	Class II
Classification:	21 CFR 888.3650: Prothesis, Shoulder, Non-Constrained, Metal/Polymer Cemented
Product Codes:	KWT, PHX, HSD
Indications for Use:	The AGILON® XO Shoulder Replacement System is indicated for use for 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 in revision cases after an inverse shoulder has failed. It is not combined with a glenoid implant. It can also be used in primary 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.

AGILON® retentive caps invers are indicated in case of shoulder joint instability if the joint cannot be stabilized with

a regular AGILON® cap inverse in combination with a Glenosphere. Warning: The use of the AGILON® retentive caps invers entails a decrease of the Range of Motion of the prosthesis. The surgeon has to balance conscientiously the advantage of stabilization and the increased risk of scapula impingement.

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 Anatomic Total Shoulder Arthroplasty
- 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
- From Anatomic Total Shoulder Arthroplasty to Inverse (Reverse) Total Shoulder Arthroplasty
- From Anatomic Total Shoulder Arthroplasty to Hemi CTA Shoulder Arthroplasty

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 device is intended for adults.

The stems of the AGILON® XO Shoulder Replacement System are intended for cementless fixation. The glenoids of the AGILON® XO Shoulder Replacement System are intended for cemented fixation.

Device Description:

The purpose of this Traditional 510(k) is introduce into interstate commerce in the United States the ALIGON® XO Glenoid Cemented components to the AGILON XO Shoulder System. The components are a line extension to the previously cleared AGILON XO Shoulder Replacement System which add all polyethylene cemented glenoids to the current system. The components introduced with this submission are intended to mate with other previously cleared

implantcast shoulder components to make a complete prosthesis.

Predicate Device: - Fx Solutions Humeris Shoulder (K163669)

Reference Device: - AGILON XO Shoulder Replacement System (K191433)

Substantial Equivalence: The AGILON XO Shoulder System AGILON® XO Glenoid Cemented components are substantially equivalent to the glenoids of the legally marketed predicate device system, the Fx Solutions Humeris Shoulder, with respect to design and intended use. Additionally, the AGILON XO Glenoids Cemented components are substantially equivalent to components of the AGILON XO Shoulder Replacement System reference device cleared in K191433.

Performance Testing: All necessary testing has been performed for the "worst-case" components of the AGILON XO Shoulder System to assure substantial equivalence to its predicate and to demonstrate the subject devices perform as intended. All testing was performed on test units representative of or worst-case compared to the finished device. The following evaluations were conducted to characterize the devices:

- Dynamic Evaluation of Glenoid Loosening or Disassociation (ASTM F2028-17)
- Range of Motion (ROM) Evaluation

Conclusions: The AGILON XO Shoulder System subject to this submission possess the same intended use and technological characteristics as the predicate device system components. All performance testing conducted for the AGILON XO Shoulder System met the predetermined acceptance criteria or were otherwise considered acceptable. As such, the AGILON XO Shoulder System components are substantially equivalent to the predicate device for the intended use.

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222482

Device Name
AGILON XO Shoulder System

Indications for Use *(Describe)*
The AGILON® XO Shoulder Replacement System is indicated for use for 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,
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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 in revision cases after an inverse shoulder has failed. It is not combined with a glenoid implant. It can also be used in primary 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.

AGILON® retentive caps invers are indicated in case of shoulder joint instability if the joint cannot be stabilized with a regular AGILON® cap inverse in combination with a Glenosphere. Warning: The use of the AGILON® retentive caps invers entails a decrease of the Range of Motion of the prosthesis. The surgeon has to balance conscientiously the advantage of stabilization and the increased risk of scapula impingement.

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

• From Anatomic Total Shoulder Arthroplasty to Inverse (Reverse) Total Shoulder Arthroplasty
• From Anatomic Total Shoulder Arthroplasty to Hemi CTA Shoulder Arthroplasty

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 device is intended for adults.

The stems of the AGILON® XO Shoulder Replacement System are intended for cementless fixation. The glenoids of the AGILON® XO Shoulder Replacement System are intended for cemented 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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