March 10, 2025

implantcast, GmbH
% Sarah Pleaugh
Director of Regulatory Affairs
MCRA, LLC
803 7th Street NW, Floor 3
Washington, District of Columbia 20001

Re: K241944
Trade/Device Name: AGILON® XO Shoulder Replacement System
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, HSD, PHX
Dated: February 11, 2025
Received: February 11, 2025

Dear Juliane Hoppner:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2025.03.10 15:46:21 -04'00'

Farzana Sharmin, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241944

Device Name

AGILON® XO Shoulder Replacement 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:
• Multi-fragmental 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 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 device is intended for adults.
The AGILON® XO Shoulder Replacement System Titanium alloy stems are intended for cementless

fixation.
The PE-glenoids of the AGILON® XO Shoulder Replacement System are intended for cemented fixation. The glenoid cementless is intended for cementless use with the addition of screws for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name:	AGILON® XO Shoulder Replacement System
Manufacturer:	implantcast, GmbH Lüneburger Schanze 26 21614 Buxtehude, Germany
Contact:	Juliane Höppner, Director of Regulatory & Clinical & Biological Affairs implantcast, GmbH Office: 49-4161-744-135
Prepared by:	MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	July 2, 2024
Classifications:	21 CFR 888.3650, Shoulder joint metal/polymer non-constrained cemented prosthesis 21 CFR 888.3660, Shoulder joint metal/polymer semi-constrained cemented prosthesis 21CFR 888.3690, Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Common Name:	Shoulder Prosthesis
Class:	II
Product Codes:	KWT, HSD, PHX
Primary Predicate:	AGILON® XO Shoulder Replacement System (K231657)
Additional Predicate:	AGILON® XO Shoulder Replacement System (K222482) AGILON® XO Shoulder Replacement System (K191433)

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:

- Multi-fragmental 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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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:

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- 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 device is intended for adults.

The AGILON® XO Shoulder Replacement System Titanium alloy stems are intended for cementless fixation.

The PE-glenoids of the AGILON® XO Shoulder Replacement System are intended for cemented fixation. The glenoid cementless is intended for cementless use with the addition of screws for fixation.

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 options depending upon the size and anatomical needs of each patient. The subject submission is for new cancellous screws for use in a total reverse shoulder replacement with the previously cleared K231657 components:

- Humeral Head Components
- Glenoid and Glenosphere Components
- Humeral Stems and Stem Extension Pieces
- Metaphyseal Components
- Fixation and Cancellous Screws

The subject line extension components are intended for use with previously cleared AGILON XO Shoulder System instruments. There are no changes to packaging, sterility, shelf life, or materials subject to this submission.

Predicate Device:
implantcast submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, AGILON® XO Shoulder Replacement System is substantially equivalent in indications, design principles, and performance to the predicate AGILON® XO Shoulder Replacement System (K231657).

Performance Testing Summary:
Engineering analysis and a review of the previously completed testing of the predicate AGILON XO Shoulder Replacement System demonstrated no new worst-case was created for the system of devices requiring new construct testing. The new cancellous screws were fully characterized per ASTM F543 testing:

- Torsional Properties
- Driving Torque
- Axial Pull-out Strength

The testing demonstrated sufficient performance for the intended use, met the predetermined acceptance criteria, and supports substantial equivalence.

The biocompatibility evaluation was completed per ISO 10993-1.

The cleaning, sterilization, packaging, shelf-life, and endotoxin testing were leveraged from the predicate AGILON® XO Shoulder Replacement System (K231657).

Substantial Equivalence Conclusion:
The data included in this submission demonstrate substantial equivalence to the predicate device. AGILON® XO Shoulder Replacement System is as safe, as effective, and performs as well as, or better, than the predicate device.