March 30, 2026

Implantcast GmbH
% Ryan Sexton
Manager, Regulatory Affairs
MCRA, LLC
803 7th St. NW, 3rd Floor
Washington, District of Columbia 20001

Re: K260037
Trade/Device Name: implantcast Packaging System Update
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH, KWY, OQI, HSD, PHX, HSX, JDI, KWT, JWH
Dated: January 6, 2026
Received: January 6, 2026

Dear Ryan Sexton:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

LIMIN SUN -S

Limin Sun, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260037

Please provide the device trade name(s).

implantcast Packaging System Update

Please provide your Indications for Use below.

EcoFit® Hip System – K163577
The EcoFit® Hip System is indicated for use as a total hip replacement in cases of:

• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The EcoFit® Hip Stem and EcoFit® Acetabular Cup is intended for uncemented, press-fit fixation.
EcoFit® Vit E Acetabular System (portfolio expansion) – K180263
The EcoFit® Hip System is indicated for use as a total hip replacement in cases of:

• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The EcoFit® Hip Stem and EcoFit® Acetabular Cup is intended for uncemented, press-fit fixation.
MUTARS® Proximal Femur Replacement System – K181778
The MUTARS® Proximal Femur Replacement System is a modular hip replacement system offering various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient.

The MUTARS® Proximal Femur System is intended to for uncemented use in total hip arthroplasty for the following indications:

• Proximal femur replacement in oncology cases where radical resection and replacement of bone is required.
• Limb salvage procedures including surgical intervention for severe trauma, failed previous prosthesis, and/or oncology indications, where radical resection and replacement of the bone is required.

Use of the prosthesis is generally only indicated in skeletally mature patients.

AGILON® XO Shoulder Replacement System – K191433
The AGILON® XO Shoulder Replacement System is indicated for use for cementless or cemented 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® 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 be used in primary and revision cases.

The main indications for the implantation of an AGILON® inverse 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

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.
ic-Bipolar Head System – K191569
The ic-Bipolar Heads is for uncemented use in conjunction with the MUTARS® Proximal Femoral Replacement System for the following indications:
• Proximal femur replacement in oncology cases where radical resection and replacement of bone is required.
• Limb salvage procedures including surgical intervention for severe trauma, failed previous prosthesis, and/or oncology indications, where radical resection and replacement of the bone is required.

Use of this prosthesis is generally only indicated in skeletally mature patients.

The ic-Bipolar Heads is for uncemented use in conjunction with the EcoFit® Hip System for the following indications:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
MUTARS® Cemented Femoral Stem (portfolio expansion) – K200045
The MUTARS® Proximal Femur Replacement System is a modular hip replacement system offering various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient.
The MUTARS® Proximal Femur System is intended for cemented and uncemented use in total hip arthroplasty or hemiarthroplasty for the following indications:
• Proximal femur replacement in oncology cases where radical resection and replacement of bone is required.
• Limb salvage procedures including surgical intervention for severe trauma, failed previous prosthesis, and/or oncology indications, where radical resection and replacement of the bone is required.

Use of the prosthesis is generally only indicated in skeletally mature patients.
ACS® LD Uni FB Knee System – K203341
The ACS® LD Uni FB Knee System is indicated for partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

This device is single-use implant intended for implantation with bone cement.
EcoFit® Hip System (portfolio expansion) – K203420
Acetabular Inserts
The EcoFit® Hip System is indicated for use as a total hip replacement in cases of:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The EcoFit® Acetabular Cup is intended for uncemented, press-fit fixation.

The MUTARS® Proximal Femur Replacement System is a modular hip replacement system offering various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient.

The MUTARS® Proximal Femur System is intended to for uncemented use in total hip arthroplasty or hemiarthroplasty for the following indications:
• Proximal femur replacement in oncology cases where radical resection and replacement of bone is required.
• Limb salvage procedures including surgical intervention for severe trauma, failed previous prosthesis, and/or oncology indications, where radical resection and replacement of the bone is required.

Femoral Stems
The EcoFit® Hip System is indicated for use as a total hip replacement in cases of:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;

• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The EcoFit® Hip Stem is intended for uncemented, press-fit fixation.

The ic-Bipolar Head System is intended for uncemented use in hemiarthroplasty, where the femoral head requires replacement but the acetabulum does not, in conjunction with the EcoFit® Hip System and MUTARS® Proximal Femur Replacement Systemor the following indications:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
implaFit® hip stems – K210678
The implaFit® hip stems are indicated for use in cases of:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The implaFit® hip stems, when used in conjunction with the ic-Bipolar Heads, are intended for the following indications:

• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

The implaFit® hip stems cementless are intended for uncemented, press-fit fixation. The implaFit® hip stems cemented are intended for cemented fixation.
AGILON XO Shoulder System (portfolio expansion) – K222482
The AGILON® XO Shoulder Replacement System is indicated for use for cementless 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.
BethaLoc® stem cementless HA – K223103
The EcoFit®, implaFit® and BethaLoc® hip stems are indicated for use in cases of:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.
The EcoFit®, implaFit® and BethaLoc® hip stems, when used in conjunction with the ic-Bipolar Heads, are intended for the following indications:

• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis

• Correction of functional deformity
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

The EcoFit® hip stems, the implaFit® hip stems cementless and the BethaLoc® hip stems are intended for uncemented, press-fit fixation.
The implaFit® hip stems cemented are intended for cemented fixation.
The ic-Bipolar Head System is intended for uncemented use in hemiarthroplasty, where the femoral head requires replacement but the acetabulum does not, in conjunction with the BethaLoc® hip stems and EcoFit® Hip System for the following indications:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
Actinia® hip stems – K232371
The Actinia® hip stems are intended to be used in total hip arthroplasty for the following indications:

• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are un-manageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The Actinia® hip stems cementless are intended for uncemented, press-fit fixation.

The Actinia® hip stems are intended to be used in partial (hemi) hip arthroplasty in conjunction with the ic-Bipolar Head System for the following indications:

• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Correction of functional deformity;
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
AGILON® XO Shoulder Replacement System (portfolio expansion) – K231657
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 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.

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 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 glenoids cementless are intended for cementless use with the addition of screws for fixation.

MUTARS® femoral stem cemented 160 mm and 200 mm (portfolio expansion) – K240391
The MUTARS® Proximal Femur Replacement System is a modular hip replacement system offering various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient.
The MUTARS® Proximal Femur System is intended for cemented and uncemented use in total hip arthroplasty or hemiarthroplasty for the following indications:
- Proximal femur replacement in oncology cases where radical resection and replacement of bone is required.
- Limb salvage procedures including surgical intervention for severe trauma, failed previous prosthesis, and/or oncology indications, where radical resection and replacement of the bone is required.

Use of this prosthesis is generally only indicated in skeletally mature patients.

EcoFit® short stem cementless cpTi (portfolio expansion) – K240834
The EcoFit® hip stems are intended to be used in total hip arthroplasty for the following indications:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The EcoFit® hip stems are intended for uncemented, press-fit fixation.

The EcoFit® hip stems are intended to be used in partial (hemi) hip arthroplasty in conjunction with the ic-Bipolar Head System for the following indications:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
ACS® LD FB Knee System – K234044
General total knee arthroplasty indications include:

• Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
• Post-traumatic loss of knee joint configuration and function
• Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function
• Revision of previous unsuccessful knee replacement or other procedure, where soft tissue stability is adequate
• Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques

The posterior stabilized variant is also indicated for PCL instability requiring implant bearing surface geometries with increased anterior-posterior constraint and absent or non-functioning posterior cruciate ligament.

The ACS® LD FB Knee System is intended for cemented use, single use only.

The ACS® LD FB Knee System is intended for use in total knee arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged knee joint articulation where there is evidence of sufficient sound bone to seat and support the components.

AGILON® XO Shoulder Replacement System (portfolio expansion) – K241944

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 avascularnecrosis,
• 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-fragmentfractures (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 assalvage procedure
• From Inverse (Reverse) Total Shoulder Arthroplasty to Hemi CTA Shoulder Arthroplastyas salvage procedure
• From Anatomic Total Shoulder Arthroplasty to Inverse (Reverse) Total ShoulderArthroplasty
• 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) Summary

Device Trade Name:	implantcast Packaging System Update
Manufacturer:	implantcast GmbH Lüneburger Schanze 26, Buxtehude 21614 Germany
Primary Contact:	Mr. Ryan Sexton MCRA, LLC Manager, Regulatory Affairs rsexton@mcra.com
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Prepared by:	MCRA, LLC 803 7th Street, NW, 4th Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	23 March, 2026
Classification Name:	CFR 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Common Name:	Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented
Class:	II
Product Codes:	LZO, MEH, KWY, OQI, HSD, PHX, HSX, JDI, KWT, JWH
Primary Predicate:	implaFit® hip stem (K210678)
Additional Predicates:	EcoFit® Hip System (K163577, K180263, K203420, K240834) MUTARS® Proximal Femur Replacement System (K181778, K200045, K240391) AGILON® XO Shoulder Replacement System (K191433, K222482, K231657, K241944) ic-Bipolar Head System (K191569) ACS® LD Uni FB Knee System (K203341) BethaLoc® stem cementless HA (K223103) Actinia® hip stems (K232371)

ACS® LD FB Knee System (K234044)

Device Description:
This Traditional Premarket Notification is for an update to the packaging system of multiple previously 510(k) cleared devices. These devices include hip systems, shoulder systems, and knee systems. There have been no changes to these devices, aside from the packaging system, since the time of the clearance. The new packaging system will be introduced for all products supplied sterile.

Indications For Use:
The Indications for Use statements provided below are identical to those of each device in scope for the packaging system update:

EcoFit® Hip System – K163577
The EcoFit® Hip System is indicated for use as a total hip replacement in cases of:

• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The EcoFit® Hip Stem and EcoFit® Acetabular Cup is intended for uncemented, press-fit fixation.
EcoFit® Vit E Acetabular System (portfolio expansion) – K180263
The EcoFit® Hip System is indicated for use as a total hip replacement in cases of:

• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The EcoFit® Hip Stem and EcoFit® Acetabular Cup is intended for uncemented, press-fit fixation.
MUTARS® Proximal Femur Replacement System – K181778
The MUTARS® Proximal Femur Replacement System is a modular hip replacement system offering various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient.

The MUTARS® Proximal Femur System is intended to for uncemented use in total hip arthroplasty for the following indications:

• Proximal femur replacement in oncology cases where radical resection and replacement of bone is required.

• Limb salvage procedures including surgical intervention for severe trauma, failed previous prosthesis, and/or oncology indications, where radical resection and replacement of the bone is required.

Use of the prosthesis is generally only indicated in skeletally mature patients.

AGILON® XO Shoulder Replacement System – K191433
The AGILON® XO Shoulder Replacement System is indicated for use for cementless or cemented 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® 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 be used in primary and revision cases.

The main indications for the implantation of an AGILON® inverse 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

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.
ic-Bipolar Head System – K191569
The ic-Bipolar Heads is for uncemented use in conjunction with the MUTARS® Proximal Femoral Replacement System for the following indications:
• Proximal femur replacement in oncology cases where radical resection and replacement of bone is required.
• Limb salvage procedures including surgical intervention for severe trauma, failed previous prosthesis, and/or oncology indications, where radical resection and replacement of the bone is required.

Use of this prosthesis is generally only indicated in skeletally mature patients.

The ic-Bipolar Heads is for uncemented use in conjunction with the EcoFit® Hip System for the following indications:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
MUTARS® Cemented Femoral Stem (portfolio expansion) – K200045
The MUTARS® Proximal Femur Replacement System is a modular hip replacement system offering various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient.
The MUTARS® Proximal Femur System is intended for cemented and uncemented use in total hip arthroplasty or hemiarthroplasty for the following indications:
• Proximal femur replacement in oncology cases where radical resection and replacement of bone is required.
• Limb salvage procedures including surgical intervention for severe trauma, failed previous prosthesis, and/or oncology indications, where radical resection and replacement of the bone is required.

Use of the prosthesis is generally only indicated in skeletally mature patients.
ACS® LD Uni FB Knee System – K203341
The ACS® LD Uni FB Knee System is indicated for partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

This device is single-use implant intended for implantation with bone cement.
EcoFit® Hip System (portfolio expansion) – K203420
Acetabular Inserts
The EcoFit® Hip System is indicated for use as a total hip replacement in cases of:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The EcoFit® Acetabular Cup is intended for uncemented, press-fit fixation.

The MUTARS® Proximal Femur Replacement System is a modular hip replacement system offering various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient.

The MUTARS® Proximal Femur System is intended to for uncemented use in total hip arthroplasty or hemiarthroplasty for the following indications:
• Proximal femur replacement in oncology cases where radical resection and replacement of bone is required.
• Limb salvage procedures including surgical intervention for severe trauma, failed previous prosthesis, and/or oncology indications, where radical resection and replacement of the bone is required.

Femoral Stems
The EcoFit® Hip System is indicated for use as a total hip replacement in cases of:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The EcoFit® Hip Stem is intended for uncemented, press-fit fixation.

The ic-Bipolar Head System is intended for uncemented use in hemiarthroplasty, where the femoral head requires replacement but the acetabulum does not, in conjunction with the EcoFit® Hip System and MUTARS® Proximal Femur Replacement Systemor the following indications:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
implaFit® hip stems – K210678
The implaFit® hip stems are indicated for use in cases of:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;

• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The implaFit® hip stems, when used in conjunction with the ic-Bipolar Heads, are intended for the following indications:

• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

The implaFit® hip stems cementless are intended for uncemented, press-fit fixation. The implaFit® hip stems cemented are intended for cemented fixation.
AGILON XO Shoulder System (portfolio expansion) – K222482
The AGILON® XO Shoulder Replacement System is indicated for use for cementless 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.
BethaLoc® stem cementless HA – K223103
The EcoFit®, implaFit® and BethaLoc® hip stems are indicated for use in cases of:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.
The EcoFit®, implaFit® and BethaLoc® hip stems, when used in conjunction with the ic-Bipolar Heads, are intended for the following indications:

• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity

• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

The EcoFit® hip stems, the implaFit® hip stems cementless and the BethaLoc® hip stems are intended for uncemented, press-fit fixation.
The implaFit® hip stems cemented are intended for cemented fixation.
The ic-Bipolar Head System is intended for uncemented use in hemiarthroplasty, where the femoral head requires replacement but the acetabulum does not, in conjunction with the BethaLoc® hip stems and EcoFit® Hip System for the following indications:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
Actinia® hip stems – K232371
The Actinia® hip stems are intended to be used in total hip arthroplasty for the following indications:

• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are un-manageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The Actinia® hip stems cementless are intended for uncemented, press-fit fixation.

The Actinia® hip stems are intended to be used in partial (hemi) hip arthroplasty in conjunction with the ic-Bipolar Head System for the following indications:

• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Correction of functional deformity;
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
AGILON® XO Shoulder Replacement System (portfolio expansion) – K231657
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 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.

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 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 glenoids cementless are intended for cementless use with the addition of screws for fixation.

MUTARS® femoral stem cemented 160 mm and 200 mm (portfolio expansion) – K240391
The MUTARS® Proximal Femur Replacement System is a modular hip replacement system offering various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient.
The MUTARS® Proximal Femur System is intended for cemented and uncemented use in total hip arthroplasty or hemiarthroplasty for the following indications:
- Proximal femur replacement in oncology cases where radical resection and replacement of bone is required.
- Limb salvage procedures including surgical intervention for severe trauma, failed previous prosthesis, and/or oncology indications, where radical resection and replacement of the bone is required.

Use of this prosthesis is generally only indicated in skeletally mature patients.

EcoFit® short stem cementless cpTi (portfolio expansion) – K240834
The EcoFit® hip stems are intended to be used in total hip arthroplasty for the following indications:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
• Rheumatoid arthritis;
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
• Revision of previously failed total hip arthroplasty.

The EcoFit® hip stems are intended for uncemented, press-fit fixation.

The EcoFit® hip stems are intended to be used in partial (hemi) hip arthroplasty in conjunction with the ic-Bipolar Head System for the following indications:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity
• Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
ACS® LD FB Knee System – K234044
General total knee arthroplasty indications include:

• Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
• Post-traumatic loss of knee joint configuration and function
• Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function

• Revision of previous unsuccessful knee replacement or other procedure, where soft tissue stability is adequate
• Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques

The posterior stabilized variant is also indicated for PCL instability requiring implant bearing surface geometries with increased anterior-posterior constraint and absent or non-functioning posterior cruciate ligament.

The ACS® LD FB Knee System is intended for cemented use, single use only.

The ACS® LD FB Knee System is intended for use in total knee arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged knee joint articulation where there is evidence of sufficient sound bone to seat and support the components.

AGILON® XO Shoulder Replacement System (portfolio expansion) – K241944

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 avascularnecrosis,
• 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-fragmentfractures (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 assalvage procedure
• From Inverse (Reverse) Total Shoulder Arthroplasty to Hemi CTA Shoulder Arthroplastyas salvage procedure
• From Anatomic Total Shoulder Arthroplasty to Inverse (Reverse) Total ShoulderArthroplasty
• 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.

Technological Comparison:
implantcast intends to introduce a new packaging system for all 510(k)-cleared implantcast devices that are supplied sterile. The packaging system is the only change being made for all these devices. There are no impacts by the new packaging system on the safety or efficacy of each device in scope. Therefore, the in-scope devices utilizing the new packaging system are substantially equivalent to the same respective devices utilizing the current packaging system.

No technological characteristics of the predicate devices are impacted by introducing the new packaging system.

Performance Testing Summary:
The performance testing specific to each device is not impacted by the update to the packaging system; therefore, it remains identical to what has been presented within the previous respective 510(k).

The packaging system has been separately validated by testing in accordance with ISO 11607-1 and ISO 11607-2 to ensure that the performance of the packaging system fulfills all the requirements after sterilization. Supplementary sterilization validations were also successfully

carried out for gamma irradiation in accordance with ISO 11137-1 and ISO 11137-2, as well as for ethylene oxide in accordance with ISO 11135.

The performance testing supports that the new packaging system is substantially equivalent to the packaging system currently used for implantcast hip systems, shoulder systems, and knee systems that are provided sterile.

Conclusion:
The subject device and the predicate devices have the same intended use, same technological characteristics, and are made of similar materials. The performance testing supports that the new packaging system and predicate packaging system are substantially equivalent.