May 12, 2025

3D-Side
Florence Allé
Design & Development Director
Daalstraat 4
Maaseik, 3680
Belgium

Re: K243509
Trade/Device Name: Archer PSI System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: QHE, KWS, PHX
Dated: April 11, 2025
Received: April 11, 2025

Dear Florence Allé :

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: 2025.05.12 16:26:38 -04'00'

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
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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)*

K243509

Device Name

Archer PSI System

Indications for Use *(Describe)*

Archer^{R} PSI System is indicated as an orthopedic instrument to assist the physician in the intra-operative positioning of total shoulder replacement components and in guiding the drill and the cut of the bone.

Archer^{R} PSI System must only be used conjointly with Archer™ CSR Total Shoulder (K152825, K173812, K181287, K182500, K191811), Catalyst EA Convertible Stemmed Shoulder (K222317) and Archer™ R1 Reverse (K202611, K211991, K213349, K223655, K232583) components in the context of primary total shoulder replacement and following a delto-pectoral approach only. Archer^{R} PSI System is manufactured from a pre-operative planning validated by the surgeon in the 'Archer™ 3D Targeting' platform (K213779). Archer^{R} PSI System is indicated for patient population fulfilling the Archer™ CSR Total Shoulder, Catalyst EA Convertible Stemmed Shoulder and Archer™ R1 Reverse indications and for which CT images are available with identifiable placement anatomical landmarks and compliant with imaging protocol provided by Archer 3D Targeting.

The device is intended for single use only.

The device is intended for adult patients.

The device has to be used by a physician trained in the performance of surgery.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 (21CFR807.92)

SUBMITTER

Company Name: 3D-Side
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Summary date: May 8, 2025

DEVICE NAME

Device trade name: Archer PSI System
Common name: Shoulder Arthroplasty Implantation System
Classification name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulation number: 21 CFR 888.3660
Classification product code: QHE
Subsequent product code: KWS, PHX

LEGALLY MARKETED PREDICATE DEVICE(S)

The predicate device to which substantial equivalence is claimed:

Item	Description
Device Classification Name	Shoulder Prosthesis, Reverse Configuration
Device Trade Name	MyShoulder™ Placement Guides
510(k) number	K190738
Original Applicant	Medacta International SA
Regulation Number	21 CFR 888.3660, 21 CFR 888.3690, and 21 CFR 888.3670
Decision date	November 13, 2019
Classification product code	PHX
Classification product code (secondary)	KWS, HSD, MBF
510(k) Review Panel	Orthopedic

Reference devices:

Trade name	510(k) number	Regulation number	Classification product code
Catalyst CSR Shoulder System	K152825	888.3650	KWT
Catalyst CSR 3 Peg Glenoids	K173812	888.3650	KWT
Catalyst CSR Shoulder System	K181287	888.3650	KWT
Catalyst CSR Press-Fit Humeral Components	K182500	888.3650	KWT
Catalyst OrthoScience CSR Shoulder System	K191811	888.3650	KWT
Catalyst EA Convertible Stemmed Shoulder	K222317	888.3660	KWS
Catalyst OrthoScience R1 Reverse Shoulder System	K202611	888.3660	PHX
Catalyst OrthoScience R1 Reverse Shoulder System	K211991	888.3660	PHX
Catalyst OrthoScience R1 Reverse Shoulder System	K213349	888.3660	PHX
Catalyst OrthoScience R1 Reverse Shoulder System	K223655	888.3660	PHX
Catalyst OrthoScience R1 Reverse Shoulder System	K232583	888.3660	PHX

DEVICE DESCRIPTION SUMMARY

The "Archer PSI System" device is a patient-matched additively manufactured single use surgical instrument (PSI). Archer PSI System is an instrument set containing a glenoid guide and its bone model and/or a humeral guide and its bone model. This patient-specific medical device is designed to fit the patient's anatomy to transfer a patient-specific pre-operative plan to the operating room. It is intended for surgical interventions in orthopaedic procedures for total shoulder arthroplasty.

The Archer PSI system instruments are designed from a draft treatment plan available via the Archer™ 3D Targeting' platform. Based on computed tomography (CT) of the shoulder anatomy, 3D CAD models of the bones and positioning and sizing of the glenoid and humeral components are submitted for evaluation to the surgeon. Upon the surgeon's approval, the guides and bone models are designed based on the validated planning and are manufactured using additive manufacturing.

INDICATIONS FOR USE

Archer^{R} PSI System is indicated as an orthopedic instrument to assist the physician in the intra-operative positioning of total shoulder replacement components and in guiding the drill and the cut of the bone.

Archer^{R} PSI System must only be used conjointly with Archer™ CSR Total Shoulder (K152825, K173812, K181287, K182500, K191811), Catalyst EA Convertible Stemmed Shoulder (K222317) and Archer™ R1 Reverse (K202611, K211991, K213349, K223655, K232583) components in the context of primary total shoulder replacement and following a delto-pectoral approach only.

Archer^{R} PSI System is manufactured from a pre-operative planning validated by the surgeon in the 'Archer™ 3D Targeting' platform (K213779). *Archer^{R} PSI System* is indicated for patient population fulfilling the Archer™ CSR Total Shoulder, Catalyst EA Convertible Stemmed Shoulder and Archer™ R1 Reverse indications and for which CT images are available with identifiable placement anatomical landmarks and compliant with imaging protocol provided by Archer 3D Targeting.

The device is intended for single use only.
The device is intended for adult patients.
The device has to be used by a physician trained in the performance of surgery.

COMPARISON WITH THE PREDICATE DEVICE

The subject and predicate devices share the same intended use. Both are orthopedic instruments designed to assist with instrumentation positioning during total shoulder arthroplasty procedures (anatomic and reverse configurations) performed via the deltopectoral surgical approach.

They are manufactured from polyamide using additive manufacturing techniques, based on pre-operative planning validated by the surgeon through a pre-operative planning software. These instruments are compatible with specific total shoulder replacement implant components and their associated accessories.

The subject and predicate devices are comparable in terms of design characteristics, including contact surfaces and key functional features. However, the cut slot characteristics of the anatomic humeral component differ between the two systems due to differences in the geometry of the compatible humeral components.

SUMMARY OF NON-CLINICAL AND CLINICAL PERFORMANCE DATA

The following assessments have been conducted to demonstrate that the subject device is substantially equivalent to the reference devices and performs in accordance with its intended use:

- Biocompatibility assessment
- Cleaning and sterilization validations
- Manufacturing cleaning validation
- Packaging and Shelf-life validation
- Intra- and Inter-Designer Variability testing
- Mechanical Integrity (Post-Processing) testing
- Debris Generation testing

Cadaveric testing was executed to demonstrate the substantial equivalence between the two techniques (manual and PSI, for both anatomic and for reverse techniques) to validate the use of the subject device for the addressed surgical techniques.

CONCLUSION

The nonclinical and cadaver testing demonstrates that the subject device, Archer PSI System, is substantially equivalent to the predicate device cleared under K190738.