Stryker GmbH
Jonathan Schell
Sr. Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430
USA

December 16, 2020

Re: K202289
Trade/Device Name: ReUnion Reversible Fracture System (RFX), ReUnion Reverse Shoulder Arthroplasty System (RSA), ReUnion Total Shoulder Arthroplasty System (TSA)
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD, PHX
Dated: November 9, 2020
Received: November 12, 2020

Dear Jonathan Schell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Michael Owens
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202289

Device Name
ReUnion Reversible Fracture System (RFX)

Indications for Use *(Describe)*

The ReUnion RFX System includes a Reversible Fracture Stem (RFX Stem) that can utilize either the ReUnion Total Shoulder Arthroplasty (TSA) or ReUnion Reverse Shoulder Arthroplasty (RSA) humeral and glenoid components and is indicated for use as a hemi, total or reverse shoulder replacement. The ReUnion RFX stem is intended for cemented use only.

When used with ReUnion TSA Humeral & Glenoid Components

The ReUnion RFX System, when used with ReUnion TSA Humeral and Glenoid components, is indicated for use as a Hemi or Total Shoulder Replacement:

• Aseptic necrosis of the humeral head.
• Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis.
• Proximal humeral fractures and/or dislocation.
• Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
• Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.

In the case of revision, when ReUnion RFX humeral stems are well fixed, the system is indicated for conversion to a total shoulder arthroplasty. In conjunction with ReUnion TSA humeral and glenoid components, if the natural glenoid provides sufficient bone stock, ReUnion RFX humeral stems can be converted from a hemiarthroplasty to a total shoulder arthroplasty, as well as revised from an existing total shoulder arthroplasty to a secondary total shoulder arthroplasty. It is also indicated for conversion to a hemiarthroplasty. In conjunction with ReUnion TSA humeral components, ReUnion RFX humeral stems can be converted from a total or reverse shoulder arthroplasty to a hemiarthroplasty, as well as revised from an existing hemiarthroplasty to a secondary hemiarthroplasty, in treatment of previously failed shoulder arthroplasty cases where revision to a reverse shoulder arthroplasty is inappropriate.

The glenoid components are intended for cemented use only.

When used with ReUnion RSA Humeral & Glenoid Components

The ReUnion RFX System, when used with ReUnion RSA humeral & glenoid components, is intended for primary, fracture, or revision total shoulder replacement. The patient’s joint must have gross rotator cuff deficiency, a functional deltoid muscle, and be anatomically and structurally suited to receive the implant(s).

• Painful, disabling joint disease of the shoulder resulting from degenerative arthritis or rheumatoid arthritis;
• Proximal humeral fractures
• Revisions of previously failed shoulder joint replacements

In the case of revision, when ReUnion RFX humeral stems are well fixed, the system is indicated for conversion to a reverse shoulder arthroplasty. In conjunction with ReUnion RSA humeral and glenoid components, ReUnion RFX humeral stems can be converted from a hemi or total shoulder arthroplasty to a reverse shoulder arthroplasty, as well as revised from an existing reverse shoulder arthroplasty to a secondary reverse shoulder arthroplasty, in treatment of a

grossly deficient rotator cuff with severe arthropathy or previously failed joint replacement with a grossly deficient rotator cuff. The patient must have a functional deltoid muscle, and be anatomically and structurally suited to receive the implant(s).

Glenoid Baseplate components are intended for cementless use with the addition of screw fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202289

Device Name
ReUnion Reverse Shoulder Arthroplasty System (RSA)

Indications for Use *(Describe)*

The ReUnion RSA Shoulder System is intended for primary, fracture, or revision of total Shoulder replacement. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The patient's joint must have gross rotator cuff deficiency, a functional deltoid muscle and be anatomically and structurally suited to receive the selected implant(s).

- Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis or rheumatoid arthritis.
- Proximal humeral fracture.
- Revision of previously failed shoulder joint replacement.

Glenoid Baseplate components are intended for cementless use with the addition of screw fixation.

The Humeral Stem components are intended for both cemented and cementless use.

In the case of revision, when ReUnion TSA humeral stems are well fixed, the system is indicated for conversion to a reverse shoulder arthroplasty.

In conjunction with ReUnion RSA humeral and glenoid components, ReUnion TSA humeral stems can be converted from a hemi or total shoulder arthroplasty to a reverse shoulder arthroplasty, as well as revised from an existing reverse shoulder arthroplasty to a secondary reverse shoulder arthroplasty, in treatment of a grossly deficient rotator cuff with sever arthropathy or previously failed joint replacement with a grossly deficient rotator cuff. The patient must have a functional deltoid muscle, and be anatomically and structurally suited to receive the implant(s).

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202289

Device Name
ReUnion Total Shoulder Arthroplasty System (TSA)

Indications for Use *(Describe)*
For use as a Hemi or Total Shoulder Replacement

• Aseptic necrosis of the humeral head.
• Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis or posttraumatic arthritis.
• Proximal humeral fracture and/or dislocation.
• Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
• Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.

Glenoid components are intended for cemented use only. The humeral stem components are intended for both cemented and cementless use.

In the case of revision, when ReUnion TSA humeral stems are well fixed, the system is indicated for conversion to a total shoulder arthroplasty. In conjunction with ReUnion TSA humeral and glenoid components, if the natural glenoid provides sufficient bone stock, ReUnion TSA humeral stems can be converted from a hemiarthroplasty to a total shoulder arthroplasty, as well as revised from an existing total shoulder arthroplasty to a secondary total shoulder arthroplasty. It is also indicated for conversion to a hemiarthroplasty. In conjunction with ReUnion TSA humeral components, ReUnion TSA humeral stems can be converted from a total or ReUnion RSA reverse shoulder arthroplasty to a hemiarthroplasty, as well as revised from an existing hemiarthroplasty to a secondary hemiarthroplasty, in treatment of previously failed shoulder arthroplasty cases where revision to a reverse shoulder arthroplasty is inappropriate.

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)

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510(k) Summary

Proprietary Name:	ReUnion Reversible Fracture System (RFX) ReUnion Reverse Shoulder Arthroplasty System (RSA) ReUnion Total Shoulder Arthroplasty System (TSA)
Common Name:	A Prosthesis, shoulder, semi-constrained, metal/polymer cemented (21 CFR 888.3660) Prosthesis, Shoulder, Hemi-Humeral, Metallic Uncemented (21 CFR 888.3690)
Regulation Description:	Shoulder joint metal/polymer semi-constrained cement prosthesis (21 CFR 888.3660) Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (21 CFR 888.3690)
Regulation Number:	21 CFR 888.3660 21 CFR 888.3690
Product Code:	KWS, HSD, PHX
Device Class:	Class II
Sponsor:	Stryker GMBH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Jonathan Schell Sr. Staff Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 Phone: 484-889-5804 Fax: 201-831-6500
Date Prepared:	August 10, 2020
Primary Predicate:	K183039: Stryker ReUnion Reverse Shoulder Arthroplasty System, ReUnion Total Shoulder Arthroplasty System, & ReUnion Reversible Fracture System

Description

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market a modified device within the ReUnion RSA System. The modification is to the:

- ReUnion RSA System to add a 2mm humeral cup component option to the existing humeral cup component options of 4mm and 10mm.

The Subject Device 2mm humeral cups have the same Intended Use and Indications for Use as the Predicate Device, and share the exact same operative technique.

ReUnion Reversible Fracture System (RFX)

The ReUnion Reversible Fracture System consists of a humeral fracture stem component which may be used in conjunction with TSA or RSA humeral and glenoid components for conventional total shoulder arthroplasty or reverse shoulder arthroplasty. It may also be used in conjunction with TSA humeral components to articulate directly with the anatomic glenoid in a hemi-shoulder application. The device contains various number of suture holes. The stems have a female taper on the proximal end of the shaft to accept TSA and RSA Gleno-humeral components. It is designed to be used in cemented applications only.

ReUnion Reverse Shoulder Arthroplasty System (RSA)

The ReUnion RSA Shoulder System is a system of components intended for total shoulder replacement in a reverse shoulder configuration. The system is comprised of a humeral cup, humeral insert, glenosphere, glenoid baseplate and screws. The Humeral Cup with the Humeral Insert are attached to the humeral side of the joint via the ReUnion TSA Humeral Stem while the Glenosphere is implanted with the Glenoid Baseplate onto the glenoid side of the joint fixated with locking Center and Peripheral Screws.

ReUnion Total Shoulder Arthroplasty System (TSA)

The Reunion Total Shoulder Arthroplasty (TSA) System is intended for shoulder arthroplasty. The components of this system consist of humeral stems, a modular humeral neck adapter, single radius humeral heads, and self-pressurizing glenoids (SPG). The humeral stem is offered in both cemented and cementless designs. The cementless humeral stem design features a circumferential Ti-plasma spray and hydroxyapatite (HA) coating at the proximal end and the cemented humeral stems have no coating at the proximal end. These humeral stems were designed to mate with the subject single radius humeral heads or the modular neck adapter, for compatibility with other marketed humeral heads. The self-pressuring glenoids (SPG) mate with the single radius heads. The SPGs are offered in both pegged and keeled configurations.

Note: ReUnion TSA Humeral Stems include both standard length ReUnion TSA stems and shorter length ReUnion S stems.

Intended Use

The ReUnion RSA, TSA and RFX Systems are intended for shoulder arthroplasty.

Indications for Use

ReUnion Reversible Fracture System (RFX)

The ReUnion RFX System includes a Reversible Fracture Stem (RFX Stem) that can utilize either the ReUnion Total Shoulder Arthroplasty (TSA) or ReUnion Reverse Shoulder Arthroplasty (RSA) humeral

and glenoid components and is indicated for use as a hemi, total or reverse shoulder replacement. The ReUnion RFX stem is intended for cemented use only.

When used with ReUnion TSA Humeral & Glenoid Components

The ReUnion RFX System, when used with ReUnion TSA Humeral and Glenoid components, is indicated for use as a Hemi or Total Shoulder Replacement:

• Aseptic necrosis of the humeral head.
• Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis.
• Proximal humeral fractures and/or dislocation.
• Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
• Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.

In the case of revision, when ReUnion RFX humeral stems are well fixed, the system is indicated for conversion to a total shoulder arthroplasty. In conjunction with ReUnion TSA humeral and glenoid components, if the natural glenoid provides sufficient bone stock, ReUnion RFX humeral stems can be converted from a hemiarthroplasty to a total shoulder arthroplasty, as well as revised from an existing total shoulder arthroplasty to a secondary total shoulder arthroplasty. It is also indicated for conversion to a hemiarthroplasty. In conjunction with ReUnion TSA humeral components, ReUnion RFX humeral stems can be converted from a total or reverse shoulder arthroplasty to a hemiarthroplasty, as well as revised from an existing hemiarthroplasty to a secondary hemiarthroplasty, in treatment of previously failed shoulder arthroplasty cases where revision to a reverse shoulder arthroplasty is inappropriate.

The glenoid components are intended for cemented use only.

When used with ReUnion RSA Humeral & Glenoid Components

The ReUnion RFX System, when used with ReUnion RSA humeral & glenoid components, is intended for primary, fracture, or revision total shoulder replacement. The patient's joint must have gross rotator cuff deficiency, a functional deltoid muscle, and be anatomically and structurally suited to receive the implant(s).

• Painful, disabling joint disease of the shoulder resulting from degenerative arthritis or rheumatoid arthritis;
• Proximal humeral fractures
• Revisions of previously failed shoulder joint replacements

In the case of revision, when ReUnion RFX humeral stems are well fixed, the system is indicated for conversion to a reverse shoulder arthroplasty. In conjunction with ReUnion RSA humeral and glenoid components, ReUnion RFX humeral stems can be converted from a hemi or total shoulder arthroplasty to a reverse shoulder arthroplasty, as well as revised from an existing reverse shoulder arthroplasty to a secondary reverse shoulder arthroplasty, in treatment of a grossly deficient rotator cuff with severe arthropathy or previously failed joint replacement with a grossly deficient rotator

cuff. The patient must have a functional deltoid muscle, and be anatomically and structurally suited to receive the implant(s).

Glenoid Baseplate components are intended for cementless use with the addition of screw fixation.

ReUnion Reverse Shoulder Arthroplasty System (RSA)

The ReUnion RSA Shoulder System is intended for primary, fracture, or revision of total Shoulder replacement. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The patient's joint must have gross rotator cuff deficiency, a functional deltoid muscle and be anatomically and structurally suited to receive the selected implant(s).
• Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis or rheumatoid arthritis.
• Proximal humeral fracture.
• Revision of previously failed shoulder joint replacement.

Glenoid Baseplate components are intended for cementless use with the addition of screw fixation.

The Humeral Stem components are intended for both cemented and cementless use.

In the case of revision, when ReUnion TSA humeral stems are well fixed, the system is indicated for conversion to a reverse shoulder arthroplasty.

In conjunction with ReUnion RSA humeral and glenoid components, ReUnion TSA humeral stems can be converted from a hemi or total shoulder arthroplasty to a reverse shoulder arthroplasty, as well as revised from an existing reverse shoulder arthroplasty to a secondary reverse shoulder arthroplasty, in treatment of a grossly deficient rotator cuff with severe arthroplasty or previously failed joint replacement with a grossly deficient rotator cuff. The patient must have a functional deltoid muscle, and be anatomically and structurally suited to receive the implant(s).

ReUnion Total Shoulder Arthroplasty System (TSA)

For use as a Hemi or Total Shoulder Replacement

• Aseptic necrosis of the humeral head.
• Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis or posttraumatic arthritis.
• Proximal humeral fracture and/or dislocation.
• Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
• Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.

Glenoid components are intended for cemented use only. The humeral stem components are intended for both cemented and cementless use.

In the case of revision, when ReUnion TSA humeral stems are well fixed, the system is indicated for conversion to a total shoulder arthroplasty. In conjunction with ReUnion TSA humeral and glenoid components, if the natural glenoid provides sufficient bone stock, ReUnion TSA humeral stems can be converted from a hemiarthroplasty to a total shoulder arthroplasty, as well as revised from an existing total shoulder arthroplasty to a secondary total shoulder arthroplasty. It is also indicated for conversion to a hemiarthroplasty. In conjunction with ReUnion TSA humeral components, ReUnion TSA humeral stems can be converted from a total or ReUnion RSA reverse shoulder arthroplasty to a hemiarthroplasty, as well as revised from an existing hemiarthroplasty to a secondary hemiarthroplasty, in treatment of previously failed shoulder arthroplasty cases where revision to a reverse shoulder arthroplasty is inappropriate.

Summary of Technologies

A comparison of the Subject Device 2mm humeral cup shows that the Subject Device is substantially equivalent to the Predicate Device regarding Intended Use, material, design, and operational principle. The modification to the Subject Device is a dimensional change to the RSA humeral cup thickness.

Non-Clinical Testing

- The Subject Device biocompatibility profile is equivalent to the Predicate Device regarding material formulation, processing, and sterilization.
- The Subject Device sterilization method and parameters remain the same as the Predicate Device.
- Fatigue Testing was performed on the Subject Device and the acceptance criteria was fulfilled.
- Engineering rationales are provided to demonstrate equivalence of the Subject Device 2mm humeral cup to the Predicate Device with respect to Taper Testing, Cup Insert Interface Testing, Fretting Corrosion, Range of Motion, and MRI Compatibility.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The Subject Device 2mm humeral cup has the same Intended Use and Indications for Use as the Predicate Device, and equivalent technological characteristics to the Predicate Device. Therefore, the information provided in this submission demonstrates substantial equivalence of the Subject Device to the Predicate Device.