DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
N/A

Device Name
Cold Shoulderz Reverse Stemless Implant Components

Indications for Use *(Describe)*
The Cold Shoulderz Reverse Stemless Implant Components are for use in adult individuals with degenerative glenohumeral joint diseases and irreparable or severely damaged rotator cuffs in which the surgeon decides reverse shoulder arthroplasty to be the preferred method of treatment.

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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Cold Shoulderz Stemless Reverse Shoulder System
510(k) Summary

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Date: November 6th, 2022

Proprietary Name: Cold Shoulderz Reverse Stemless Implant Components
Common Name: Stemless Reverse Shoulder Arthroplasty
Classification Name:

- Shoulder Prosthesis, Reverse Configuration (21 CFR Section 888.3660, Class II)

Legally Marketed Device to Which Equivalence Is Claimed:

Name	Manufacturer	501(k) Number
Equinoxe Reverse System	Exactech, Inc.	K063569
Equinoxe Stemless Shoulder	Exactech, Inc.	K173388

Indications for Use:
The Cold Shoulderz Reverse Stemless Implant Components are for use in adult individuals with degenerative glenohumeral joint diseases and irreparable or severely damaged rotator cuffs in which the surgeon decides reverse shoulder arthroplasty to be the preferred method of treatment.

Device Description:
The Cold Shoulderz Reverse Stemless Implant Components consist of:

- Glenoid anchor
- Glenoid screws
- Glenosphere
- Glenosphere tray
- Tray liner
- Humeral anchor

These parts are for use in stemless reverse total shoulder arthroplasty and the proposed modifications to the listed predicate devices are a combination of elements of the two predicates.

The proposed device shares the following with the listed predicate device:

- The same indications of use
- The same intended use
- The same materials (ultra-high molecular weight polyethylene, cobalt-chromium-molybdenum, wrought titanium 6-aluminum 4-vanadium alloy)
- The same anchor design as the Equinoxe Stemless Shoulder (K063569)
- The same glenosphere and tray design as the Equinoxe Reverse System (K173388)

Non-Clinical Testing

Testing on the Cold Shoulderz Reverse Stemless Implant Components was done in accordance with our predicate devices to meet established standards from the American Society for Testing and Materials and the International Organization for Standards. The following tests were completed:

- Range of motion (ASTM F1378-6.2)
- Axial, torque, lever out, loosening, and disassociation (ASTM 2028-17)
- Cyclic loading of forces experienced by the device
- Effect of artificial aging on the glenoid polymer (ASTM 2003-02)

Substantial Equivalence Conclusion:

Based on the results listed in this 501(k) for the indications of use, the technological characteristics and overall design, and the results of the non-clinical testing, it is concluded that all listed properties of the Cold Shoulderz Reverse Stemless Implant Components hold substantial equivalence to the referenced predicates.

Device Description:

The device consists of the following components:

- Glenoid anchor
- Glenoid screws
- Glenosphere
- Glenosphere tray
- Tray liner
- Humeral anchor

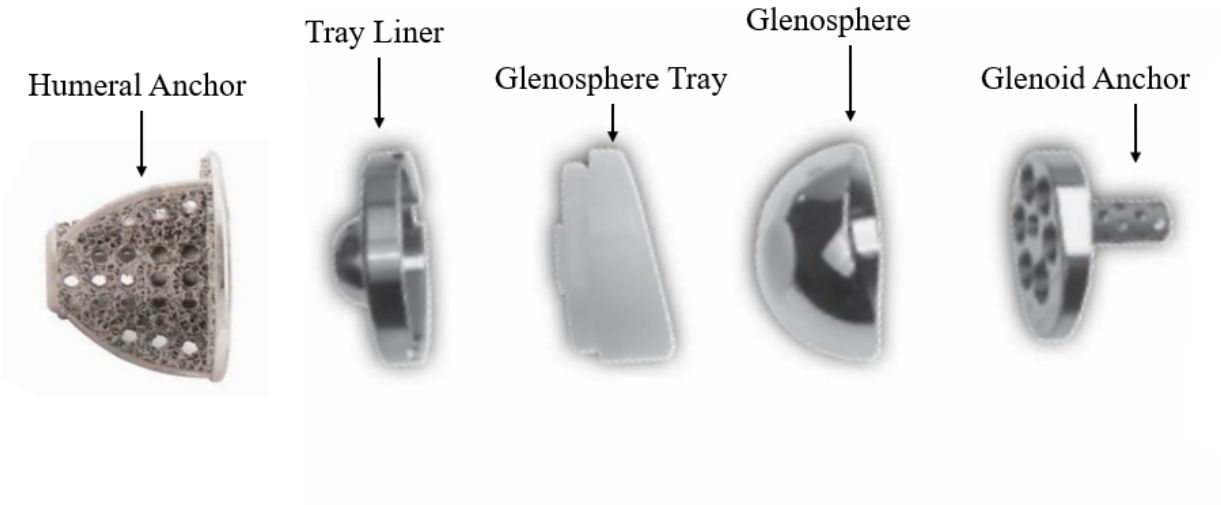


Figure 1. Labeled images of each part listed above

Every part is intended to be in contact with tissue. The humeral anchor, the glenoid anchor, the glenosphere liner, and the glenoid screws consist of Ti-6Al-4Va alloy, the glenosphere consists of Co-Ch-Mb alloy, and the tray consists of ultra-high molecular weight polyethylene. The anchors and the screws are indicated for cemented use.

Figure 2. Image of an assembled glenosphere with the screws, as if it were already implanted

The humeral anchor is indicated to be implanted into the humerus, the glenosphere liner to be attached to the humeral anchor, and the glenosphere tray to the liner. The glenoid anchor is indicated to be inserted into the bone in the glenoid cavity and further anchored in place by the glenoid screws.
The glenosphere is then to be hammered into the glenoid anchor and kept in place by friction. As the device is semi-constrained, there is no direct attachment between the glenosphere tray and the glenosphere, but the articulation of the surfaces keeps them in contact when implanted as shown in the example below.

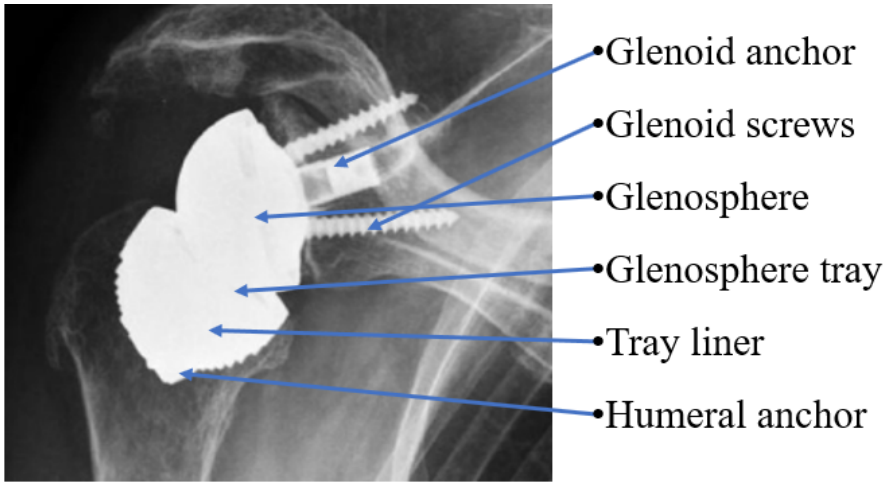


Figure 3. Example image of an existing reverse stemless implant to display complete assembled structure.

Executive Summary/Predicate Comparison

The Cold Shoulderz Reverse Stemless Implant Components includes a reverse semi-constrained prosthesis used in reverse shoulder replacement procedures. It is used in patients to reduce pain and restore arm motion in adults with degenerative diseases of the glenohumeral joint and an irreparable rotator cuff. Furthermore, it can be used in patients after a failed glenohumeral joint replacement that resulted in loss of rotator cuff function.

The Cold Shoulderz Reverse Stemless Implant Components is composed of a glenosphere, humeral anchor, glenoid anchor, glenosphere tray, glenosphere liner, and glenosphere screws. Most of the components, including glenosphere, glenoid anchor, glenosphere tray, glenosphere liner, and glenosphere screws are identical to the predicate device, Equinoxe Reverse Shoulder System. The difference between Cold Shoulderz and the predicate is the humeral component of the implant. This device has a humeral anchor that does not have a stem. The length of this component is from 17 mm to 24 mm. On the other hand, the predicate has a stemmed humeral component. The lengths for the stem part range from 175 mm to 200 mm. Other than this, the devices are identical. This can be seen in Table 1. In addition to the predicate device, a reference device also was used. The reference is a stemless implant used for anatomic total shoulder arthroplasty and, even if most components are different, the humeral component is identical to the one proposed in this device. Both predicate and reference devices can be seen in Figure 4.

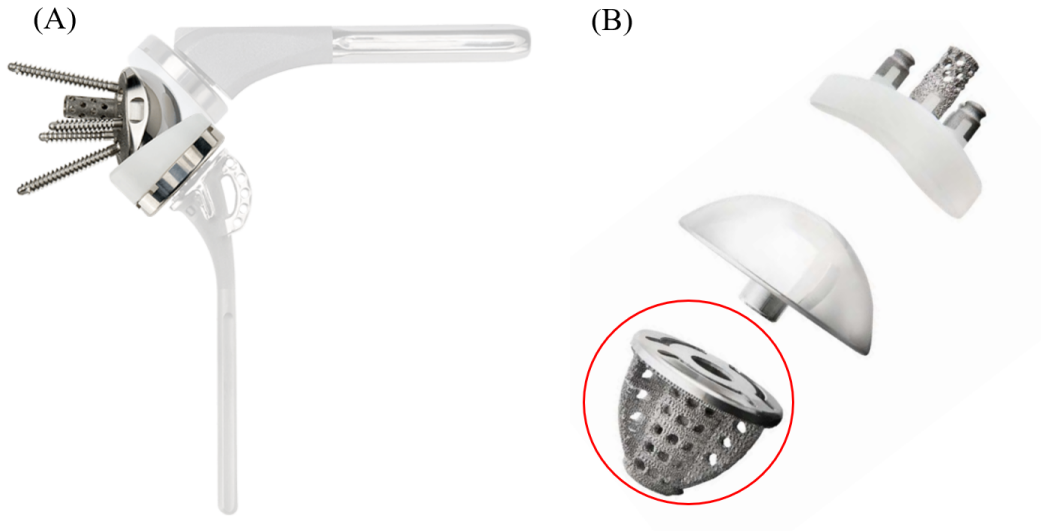


Figure 4. (A) Predicate device and Exactech's implant for reverse shoulder arthroplasty. (B) Reference device with the desired humeral component (circled in red)

Table 1: Predicate Comparison

Description	Cold Shoulderz Implant	Predicate Shoulder Implant (K063569)
Intended use	Intended for use in reverse shoulder arthroplasty for pain reduction and improved arm function for adult patients	Intended for use in reverse shoulder arthroplasty for pain reduction and improved arm function for adult patients
Indications for use	Relieve pain and restore function in adult individuals with degenerative diseases of the glenohumeral joint and an irreparable rotator cuff. Also used for failed glenohumeral joint replacement that led to loss of the rotator cuff function.	Relieve pain and restore function in adult individuals with degenerative diseases of the glenohumeral joint and an irreparable rotator cuff. Also used for failed glenohumeral joint replacement that led to loss of the rotator cuff function.
Sterility	Gamma radiation	Gamma radiation
Prosthesis type	Semi-constrained	Semi-Constrained
Humeral Components	Stemless: 17 mm,20.5 mm, and 24 mm	Stemmed: 175 mm, 215 mm, and 200 mm
Glenoid and glenosphere components	Identical	Identical
Materials	Ultra-high molecular weight polyethylene, cobalt-chromium-molybdenum, and wrought titanium 6-aluminum 4-vanadium alloy	Ultra-high molecular weight polyethylene, cobalt-chromium-molybdenum, and wrought titanium 6-aluminum 4-vanadium alloy

The performance testing carried out did not include animal or clinical testing, as the bench testing satisfied the standards from the American Society for Testing and Materials (ASTM) and the International Organization for Standards (ISO). The performance testing included range of motion, axial, torque, lever out, loosening, and dissociation tests. Furthermore, the cyclic loading of forces experienced were found. Lastly, the effect of wear out of the glenoid component was found. The results from each individual test satisfied the device standards ASTM F1378-6.2, ASTM 2028-17, and ASTM 2003-02.

Substantial Equivalence Discussion - Valeria

The predicate device is the Equinoxe Reverse Shoulder System. Its proprietary name is Exactech Equinoxe Reverse Shoulder System. The submitter for this device was Amnon Talmor and its 510(k) number is K063569. When it comes to device comparisons, the predicate and Cold Shoulderz have the same intended use, intended application, performance testing, materials, biocompatibility, sterilization, and more. This can be appreciated in Table 2. The difference between Cold Shoulderz and the Equinoxe Reverse Shoulder System is the humeral component of the implant. To illustrate, the humeral component of the Equinoxe Reverse Shoulder System has a stem (175-200 mm). Cold Shoulderz, however, integrated a humeral anchor with a much smaller size (17-24 mm).

The reference device is the Equinoxe Stemless Shoulder. Its proprietary name is Exactech Equinoxe Stemless Shoulder. The submitter for this device was Thomas McNamara and its 510(k) number is K173388. This device is used in anatomic total shoulder arthroplasty. Therefore, the intended use, indications for use, and technical characteristics are different. Even if this is the case, this device was used as a reference because one of its components was the humeral anchor, which is also in the Cold Shoulderz model. This can be seen both in Figure 1 and Figure 2.B. The reference device shows that it is safe to have a stemless implant that can be inserted in the humerus. In addition, it is important to mention that Cold Shoulderz, the predicate device, and the reference device have the same materials, sterilization methods, and biocompatibility. Lastly, the detailed technical comparison for both the reference and predicate devices can be seen in Table 2.

Table 2. Substantial Equivalence

Attribute	**Subject Device** Cold Shoulderz Reverse Stemless Implant Components	**Primary Predicate** Equinoxe Reverse System (K063569)	**Reference Device** Equinoxe Stemless Shoulder (K173388)
Product Code	PHX,KWT	PHX,KWT	PKC
Regulation Number	888.3660	888.3660	888.3660
Intended Use	Intended for use in reverse shoulder arthroplasty for pain reduction and improved arm function for adult patients	Intended for use in reverse shoulder arthroplasty for pain reduction and improved arm function for adult patients	Intended for use in total shoulder arthroplasty with Exatech glenoid components
Indications for use	Relieve pain and restore function in adult individuals with degenerative diseases of the glenohumeral joint and an irreparable rotator cuff. Also used for failed glenohumeral joint replacement that led to loss of the rotator cuff function	Relieve pain and restore function in adult individuals with degenerative diseases of the glenohumeral joint and an irreparable rotator cuff. Also used for failed glenohumeral joint replacement that led to loss of the rotator cuff function	Used in adult individuals with degenerative diseases of the glenohumeral joint where anatomic total arthroplasty is determined by the doctor to be preferred method of treatment
Intended User	Surgeons	Surgeons	Surgeons
Intended Patient Population	Patients needing Reverse Shoulder Arthroplasty	Patients needing Reverse Shoulder Arthroplasty	Patients needing anatomic total shoulder arthroplasty
Materials	Ultra-high molecular weight polyethylene, cobalt-chromium-molybdenum, and wrought titanium 6-aluminum 4-vanadium alloy	Ultra-high molecular weight polyethylene, cobalt-chromium-molybdenum, and wrought titanium 6-aluminum 4-vanadium alloy	Ultra-high molecular weight polyethylene, cobalt-chromium-molybdenum, and wrought titanium 6-aluminum 4-vanadium alloy
Humeral Component	Stemless/anchor. Sizes:17 mm, 20.5 mm, and 24 mm	Stemmed. Sizes: 175 mm, 215 mm, and 200 mm	Stemless/anchor. Sizes:17 mm, 20.5 mm, and 24 mm
Glenosphere	Same model as predicate	38 mm - 46 mm	N/A
Glenoid anchor	Exactech catalog number: 320-15-01	Exactech catalog number: 320-15-01	N/A
Glenosphere tray	38 mm, 42 mm, and 46 mm	38 mm, 42 mm, and 46 mm	N/A
Tray Liner	0, 5, 10, 15	0, 5, 10, 15	N/A
Glenoshere screws	Ranges from 4.5 x 18 mm to 4.5 x 46 mm	Ranges from 4.5 x 18 mm to 4.5 x 46 mm	N/A
Standards of Performance	ASTM F1378-6.2, ASTM 2028-17, and ASTM 2003-02	ASTM F1378-6.2, ASTM 2028-17, and ASTM 2003-02	ASTM F2565-13, ISO 5834-3 2nd. Ed. 2019-02, ASTM F2565-21
Biocompatibility	ISO 10993-10; ISO 10993-4; ISO 10993-5;	ISO 10993-10; ISO 10993-4; ISO 10993-5;	ISO 10993-10; ISO 10993-4; ISO 10993-5;
Sterilization	ISO 11137-1, USP <161>, USP <85>, ANSI/AAMI ST72	ISO 11137-1, USP <161>, USP <85>, ANSI/AAMI ST72	ISO 11137-1, USP <161>, USP <85>, ANSI/AAMI ST72

Proposed Labeling and Packaging

Labeling and Packaging will follow ISO 6018:1987.

Packaging of the Cold Shoulderz Reverse Stemless Implant

a. Each implant will be supplied clean and sterile.

b. Each implant will be packaged in a pack that will protect the implant from any possible mechanical or physical damage. If the implant has sharp edges, the proper packaging will be used to suitably protect and prevent damage.
c. If two or more implants are packaged together, each implant will be separated by suitable material.
d. Each pack shall be capable of being opened easily by hand, and such that sterile products shall be capable of being presented sterile and ready for use.
e. The outer container shall be designed so that once opened it will not permit resealing; however, if it is possible to reseal the outer container, it shall be clearly visible and labeled.

Labeling of the Cold Shoulderz Reverse Stemless Implant

The following information, if applicable to the Cold Shoulderz Reverse Stemless Implant, will appear legible and clear on each package containing the product:

a. The name, registered trademark, and address of the manufacturer
b. A description of the contents within the package; this may include names, dimensions, and material(s)
c. An indication as to whether the implant is for single use only
d. The words “Sterile unless packaged damaged” or equivalent wording/phrasing
e. An indication of the sterilization process that was used
f. If the implant/device is not to be re-sterilized
g. The recommended method of opening and handling the sterile package to ensure constant sterility
h. Whether or not storage and transportation is required
i. The expiration date (year and month) or date that the implant was manufactured, expressed in accordance with ISO 2014

Shelf life of Cold Shoulderz Reverse Stemless Implant

Cold Shoulderz Reverse Stemless Implant has a shelf life of five (5) years, with proper inventory rotation happening to ensure safety. Implants are generally shipped within one calendar year of being sterilized.

Sterilization and Shelf Life

The proposed Cold Shoulderz components and the predicate devices are provided sterile for single use only. The desired method of sterilization was gamma irradiation. This method of sterilization was considered appropriate due to the short processing time, the ability to penetrate multiple layers and types of packaging, and its compatibility with a variety of different materials. Gamma irradiation works by killing harmful bacteria through the process of destroying DNA which ultimately halts bacterial division. The gamma irradiator was a fixed system consisting of a source of radiation inside a shielded room, conveyance of the product into and out of the shielded room, and a control safety system.

ISO 11137-1 was the standard for radiation sterilization of medical devices. Additional controls include 10 CFR 37 which requires proper PPE for radioactive sources, licenses for gamma irradiators regulated at state levels and through the USNRC, Department of Homeland Security, and U.S. Department of Energy. All components are supplied sterile (through gamma irradiation) to a sterility assurance level (SAL) of 10^-6 and are intended for single use only. Never re-sterilize an implant. Re-sterilization may adversely affect the implant's materials and properties resulting in premature failure.The dose at which this product will be irradiated was established and validated according to

multiple types of tests, some of which include maximum dose testing, bioburden testing, and bacteriostasis/fungistasis (B/F) testing. Pyrogen testing was conducted in accordance with USP <161> , USP <85><85>, and ANSI/AAMI ST72 to ensure the proposed implant components meet recommended limits per FDA's Guidance Document Submission and Review of Sterility Information in Premarket (510(k)) Submission for Devices Labeled as Sterile.

Biocompatibility

The biocompatibility evaluation for the implant was conducted in accordance with the International Organization for Standardization (ISO 10993). Some specific biocompatibility tests conducted on Cold Shoulderz Reverse Stemless Implant were:

1. Sensitization and Irritation
2. Cytotoxicity
4. Hemocompatibility
5. Carcinogenicity

Sensitization and Irritation

Exposure to metal ions can result in local and systemic hypersensitivity reactions. This hypersensitivity associated with metals is most believed to be a Type IV reaction mediated by T-cells. T-cells are a type of white blood cells that participate in cell mediated immunity. The sensitization and irritation is evaluated for all metal implants regardless of the duration and type of tissue contact. This section describes the procedure for the proper assessment of medical devices and their constituent materials with regards to the possible potential to produce irritation or skin sensitization. This will closely follow ISO 10993-10 and some normative references that are indispensable for the application of this document include:

a. ISO 10993-1:2009, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
b. ISO 10993-2, Biological evaluation of medical devices — Part 2: Animal welfare requirements
c. ISO 10993-9, Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products
d. ISO 10993-12, Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
e. ISO 10993-13, Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices
f. ISO 10993-14 Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics
g. ISO 10993-15, Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys
h. ISO 10993-18, Biological evaluation of medical devices — Part 18: Chemical characterization of materials
i. ISO 14155-1, Clinical investigation of medical devices for human subjects — Part 1: General requirements
j. ISO 14155-2, Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans

Cytotoxicity

This section describes the approach to properly assess cytotoxicity. The methods will specify the incubation and culture of cells when in contact with the Cold Shoulderz Reverse Stemless Implant. The methods are designed to determine and analyze the possible biological response. Many substances and materials have a toxic effect and compounds experiencing cytotoxicity can cause major cell damage and death. The testing for cytotoxicity will closely follow ISO 10993-5. Some normative references that are essential for the application of this document when measuring cytotoxicity include:

a. ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system
b. ISO 10993-12, Biological evaluation of medical devices — Part 12: Sample preparation and reference materials

Hemocompatibility

For devices that have direct contact with circulating blood, regardless of the duration must be hemocompatible. The main and key points within hemocompatibility testing are coagulation, hemolysis, hematology, platelets, and complement system. The proper assessment of hemocompatibility usually involves static, agitated, or shear flow *in vitro* models for the incubation of blood with biomaterials. The hemocompatibility markers are then determined and measured before and after incubation of the material. To measure and analyze hemocompatibility, ISO 10993-4 will be closely followed. Other ISO standards that will aid in the application of this document include:

a. ISO 10993-1:1997, Biological evaluation of medical devices — Part 1: Evaluation and testing
b. ISO 10993-2:1992, Biological evaluation of medical devices — Part 2: Animal welfare requirements

Carcinogenicity

The assessment of carcinogenicity aids in the identification of hazards associated with the exposure to materials. This closely followed the guidelines within ISO 10993-10 and before a carcinogenicity test was conducted, ISO 10993-1 and ISO 10993-18 were also taken into account and referenced as normative references. The choice to ultimately perform a carcinogenicity test will be justified on the grounds of the assessment of the potential risk of carcinogenesis occurring due to the medical device. Carcinogenicity tests will not be performed when risks can be adequately assessed and/or managed.

When evidence was not available to dismiss carcinogenic risks, situations where this testing was needed included the following:

a. resorbable materials and medical devices for which the resorption time is greater than 30 days, unless there are significant and adequate data on human use or exposure
b. materials and medical devices introduced in the body and/or its cavities with a permanent or cumulative contact of greater than 30 days, except when significant and adequate human-use history is available

Software

This section does not apply to Cold Shoulderz Reverse Stemless Implant Components.

Electromagnetic Compatibility and Electrical Safety

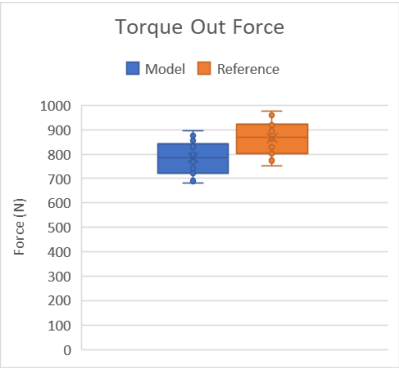
The device was not tested as the predicate device follows the standards in place by the American Society for Testing and Materials such as Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment (ASTM F2052-15), Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment (ASTM F2213-17), and Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging (ASTM F2182-19e2).

Performance Testing - Bench

Testing on the Cold Shoulderz Reverse Stemless Implant Components was done in accordance with our predicate devices to meet established standards from the American Society for Testing and Materials and the International Organization for Standards. The following tests were completed:

1. Range of motion (ASTM F1378-6.2)
2. Axial, torque, lever out, loosening, and disassociation (ASTM 2028-17)
3. Cyclic loading of forces experienced by the device
4. Effect of artificial aging on the glenoid polymer (ASTM 2003-02)

Range of motion was similar to the predicate reverse stemmed implant. Axial, torque and lever out forces did not show any significant changes between the reference stemless implant and the new reverse stemless implant and no additional loosening or disassociation from the bone as shown in figures 5, 6, and 7. An example of the lever out system that was used to conducted testing is shown in figure 8.



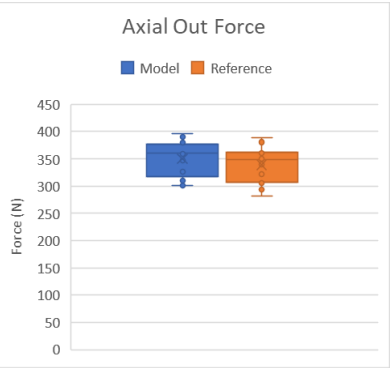


Figure 5 (Left) - Lever out force graphs of the Cold Shoulderz Reverse Implant versus the reference anatomic reverse implant. **Figure 6 (Middle)** - Torque out force graphs of the Cold Shoulderz Reverse Implant versus the reference anatomic reverse implant. **Figure 7 (Right)** - Axial out force graphs of the Cold Shoulderz Reverse Implant versus the reference anatomic reverse implant.

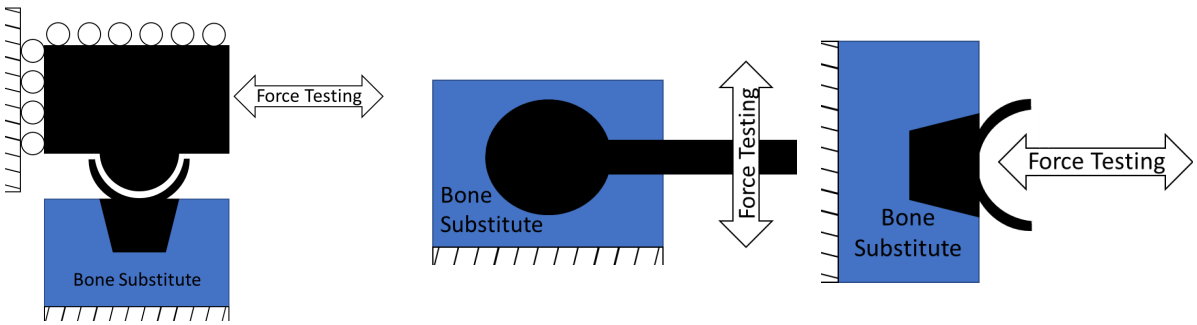


Figure 8 (Left)- Example of the system used to measure the lever out force required. **Figure 9 (Middle)**- Example of the system used to measure the torque out force required. **Figure 10 (Right)**- Example of the system used to measure the axial out force required.

For the lever out system, the height of the head is adjustable and then is fixed once in the correct position. The head is then attached to a slider which will read the applied force. The force at failure is then recorded to compare against previous devices in the same bone substitute. For the torque out system, a bar is attached to the glenoid and is rotated with increasing force until failure is reached. For the axial out system, the force meter is attached directly to the glenoid and is pulled out parallel to the direction of implantation.

All other tests showed no significant differences between the predicate and reference devices as the materials are the same.

Performance testing - Animal

Animal testing is not applicable as arm motion, size, and physiology is not the same for animals and humans.

Performance testing - Clinical

Clinical testing was not necessary as the materials used and performance testing carried out are the same as the predicate device. No further testing was needed to determine substantial equivalence.