Symmetry Medical Manufacturing Inc. DBA Tecomet, Inc.
% David Furr
Consultant
FDC Services LLC
8708 Capehart Cove
Austin, Texas 78733

August 4, 2021

Re: K211553
Trade/Device Name: Tecomet Global Unite Short Stem Instrumentation
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, HSD
Dated: June 8, 2021
Received: June 10, 2021

Dear David Furr:

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

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)*
K211553

Device Name
Tecomet Global Unite Short Stem Instrumentation

Indications for Use *(Describe)*

The Tecomet Global Unite Short Stem Instrumentation (GUSS) are intended to be used to implant the DePuy GLOBAL UNITE Shoulder System Short Stem Shoulder, in accordance with its cleared indications for use and contraindications.

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.

510(k) Premarket Notification
Tecomet Global Unite Short Stem Instrumentation

510(k) Summary

Date: July 29, 2021

1. Submitted By: Symmetry Medical Manufacturing Inc. DBA Tecomet, Inc.
3724 North State Road 15
Warsaw, Indiana 46582
(574) 267-8700

2. Contact: David C. Furr
8708 Capehart Cove
Austin, Texas 78733
512-906-9654

3. Product: Tecomet Global Unite Short Stem Instrumentation Product codes: PHX - Class II (21 CFR 888.3660)
KWS - Class II (21 CFR 888.3660)
HSD - Class II (21 CFR 888.3960)

4. Common/Classification Name: Shoulder Arthroplasty Instruments

Predicate devices: DePuy GLOBAL UNITE Platform Shoulder System K170748
DePuy Delta Xtend Reverse Shoulder System K192855

Description:

The Tecomet Global Unite Short Stem Instrumentation (GUSS) is intended only for use as surgical instrumentation for the DePuy GLOBAL UNITE Shoulder System Short Stem Shoulder. Tecomet manufactures this instrumentation exclusively for DePuy. The instrumentation is intended to be used with the GLOBAL UNITE Short Stem Shoulder System which was cleared separately under premarket notification K202098 (K202098 did not include instruments). The Tecomet GUSS instruments are a combination of Class I General Use Instruments, Class II Short Stem Shoulder-specific instruments and a Class II Sterilization Tray. The instruments include Humeral Stem Brosteotomes in 8mm-16mm sizes, a Stem Wrench, 155º Proximal Reaming Guides, 145º Proximal Reaming Guides, Bullet Tip Reamers and a sterilization tray. Although the tray is included in the system, it is not the subject of this premarket notification. The tray is already cleared by the Tecomet (Symmetry Medical) 510(k) K012105 (Polyvac Surgical Instrument Delivery System).

The Tecomet Global Unite Short Stem Instrumentation (GUSS) is all manufactured from 17-4 PH SST Stainless Steel. The instruments are exclusively for, and must be used in accordance with the DePuy GLOBAL UNITE Platform Anatomic and Reverse Shoulder Surgical Technique. The devices are reusable and must be sterilized by the user prior to use.

510(k) Premarket Notification
Tecomet Global Unite Short Stem Instrumentation

Indications for Use:

The Tecomet Global Unite Short Stem Instrumentation (GUSS) are intended to be used to implant the DePuy GLOBAL UNITE Shoulder System Short Stem Shoulder, in accordance with its cleared indications for use and contraindications.

Comparison of Technological Characteristics:

The Tecomet Global Unite Short Stem Instrumentation (GUSS) is substantially equivalent to the reaming, sizing and positioning instrumentation included in the GLOBAL UNITE Platform Shoulder System (K170748) and The DePuy Delta Xtend Reverse Shoulder System (K192855). The predicate devices are entire shoulder systems; however, the subject devices are only instruments. 145º reaming guide predicates were included in K170748 and 155º reaming guide predicates were under K192855.

The subject instruments and predicate instruments are made from the same material and are used in a similar fashion.

Element of Comparison	510(k) Device: Tecomet Global Unite Short Stem Instrumentation	Predicate Devices: DePuy GLOBAL UNITE Platform Shoulder System (K170748) DePuy Delta Xtend Reverse Shoulder System (K192855)	Comparison
Regulation and Product Classification Code	PHX, KWS, HSD - Class II (21 CFR 888.3660 & 21 CFR 888.3690)	PHX, KWS, HSD - Class II (21 CFR 888.3660 & 21 CFR 888.3690)	Same
Indications for Use	The Tecomet Global Unite Short Stem Instrumentation (GUSS) are intended to be used to implant the DePuy GLOBAL UNITE Shoulder System Short Stem Shoulder, in accordance with its cleared indications for use and contraindications.	Refer to K170748 & K192855 All predicate device indications are shoulder arthroplasty	Subject device is not for implantation but is similar to instrumentation in the predicates. Predicate shoulder system indications do not detail instrumentation.
Principal Material of Construction (instruments only)	The Tecomet Global Unite Short Stem Instrumentation (GUSS) is all manufactured from 17-4 PH SST Stainless Steel	17-4 PH SST Stainless Steel	Same
Humeral Component Instrument Configuration	Bullet tip reamers, brosteotomes, reaming guides, stem wrench and instrument tray	Bullet tip reamers, brosteotomes, reaming guides, stem wrench and instrument tray	Configuration is identical; subject devices include short-stem sizes: 145º reaming guide predicates were included in K170748 and 155º reaming guide predicates were under K192855.
Sterilization	Prevacuum Steam 4 minute cycle 132ºC	Prevacuum Steam 4 minute cycle 132ºC	Same

510(k) Premarket Notification
Tecomet Global Unite Short Stem Instrumentation

Summary of Non-Clinical Testing:

The following testing was conducted or is referenced to establish efficacy.

Type of Testing	Primary Standard(s) Used (as applicable)	Acceptance Criteria	Test Result
Pre-vacuum sterilization efficacy 3 minutes at 132ºC	AAMI ST77 Containment Devices for Reusable Medical Device Sterilization ISO 17665-1 Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	10^{-6} SAL	PASSED
Pre-vacuum dry time 3 minutes	AAMI ST77 Containment Devices for Reusable Medical Device Sterilization ISO 17665-1 Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	Establish Minimum Dry Time	40 minutes
Pre-vacuum dry time 4 minutes	AAMI ST77 Containment Devices for Reusable Medical Device Sterilization ISO 17665-1 Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	Establish Minimum Dry Time	40 minutes
Design Validation	N/A design validation cadaver testing	Acceptable performance for reverse and anatomic shoulder preparation	PASSED

The Tecomet Global Unite Short Stem Instrumentation (GUSS) is identical in material to the corresponding predicate device instrumentation GLOBAL UNITE Platform Shoulder System. Cytotoxicity testing per ISO 10993-5, Irritation testing per ISO 10993-10, Sensitization testing per ISO 10993-10 was conducted and justifications for not performing acute systemic toxicity and material mediated pyrogenicity testing were provided.

Conclusion

The results of the non-clinical testing and evaluations have demonstrated that the subject devices are substantially equivalent to the predicate devices (K170748, K192855).