TechMah Medical LLC
Mary Vater
Regulatory Consultant
Medical Device Academy, Inc.
345 Lincoln Hill Rd.
Shrewsbury, Vermont 05738

February 3, 2021

Re: K202151
Trade/Device Name: Smart SPACE Shoulder 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, OLO, MBF
Dated: August 3, 2020
Received: August 3, 2020

Dear Mary Vater:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202151

Device Name
Smart SPACE Shoulder System

Indications for Use *(Describe)*

Smart SPACE Shoulder 3D Positioner
Smart SPACE Shoulder System instrumentation consists of a patient-specific 3D positioner. It has been specially designed to assist in the intraoperative positioning of shoulder components used with total anatomic or reverse shoulder arthroplasty procedures using anatomic landmarks that are identifiable on patient-specific preoperative CT scans.

Smart SPACE Shoulder Cubit Guidance
Smart SPACE Shoulder Cubit Guidance consists of a patient-specific 3D mapper, single use instrumentation, and an intraoperative guidance software. They have been specially designed to assist in the intraoperative positioning of shoulder components used with total anatomic or reverse shoulder arthroplasty procedures using anatomic landmarks that are identifiable on patient-specific preoperative CT scans.

Smart SPACE Shoulder Planner software
Smart SPACE Shoulder Planner software is a medical device for surgeons composed of one software component. It is intended to be used as a pre-surgical planner for shoulder orthopedic surgery.
Smart SPACE Shoulder Planner software runs on standard personal and business computers running Microsoft Windows operating system.
The software supports DICOM standard to import the CT scan (Computed Tomography) images of the patient. Only CT scan modality can be loaded with the Smart SPACE Shoulder Planner software.
Smart SPACE Shoulder Planner software allows the surgeon to visualize, measure, reconstruct, annotate and edit anatomic data.
It allows the surgeon to design shoulder patient-specific instrumentation based on the pre-surgical plan.
The software leads to the generation of a surgical report along with a 3D file of the shoulder patient-specific instrumentation.
Smart SPACE Shoulder Planner software does not include any system to manufacture the shoulder patient-specific instrumentation.
Smart SPACE Shoulder Planner software is to be used for adult patients only and should not be used for diagnostic purposes.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

TechMah Medical LLC
2099 Thunderhead Rd., Suite 302
Knoxville, TN 37922
Tel: +1.877.725.6920 ext. 104

Primary Contact Person:	Mary Vater, 510(k) Consultant
Primary Contact Email:	mary@fdaecopy.com
Contact Person:	Mohamed R. Mahfouz, Ph.D.
Date Prepared:	July 31, 2020

II. DEVICE

Name of Device:	Smart SPACE Shoulder System
Classification Name:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer, Uncemented Orthopedic Stereotaxic Instrument
Regulation:	21 CFR §888.3660, 21 CFR §888.3670, and 21 CFR §882.4560
Regulatory Class:	Class II
Product Classification Code:	QHE, KWS, MBF, OLO

III. PREDICATE and REFERENCE DEVICES

Predicate Manufacturer:	TechMah Medical LLC
Predicate Trade Name:	SmartSPACE Shoulder System
Predicate 510(k):	K191247
Predicate Product Code:	QHE, KWS, MBF
Reference Manufacturer:	Orthosoft Inc. (d/b/a Zimmer CAS)
Reference Trade Name:	iASSIST Knee System
Reference 510(k):	K192080
Reference Product Code:	OLO

IV. DEVICE DESCRIPTION

The Smart SPACE Shoulder System consists of the Smart SPACE Shoulder Planner software which assists the user in planning reverse and anatomic total shoulder arthroplasty. In addition, a choice of intraoperative execution of the surgical plan using either a glenoid 3D positioner or Smart SPACE Shoulder Cubit Guidance. The Smart SPACE Shoulder System (subject device) is compatible with

Lima Corporate shoulder replacement implants; Verification and Validation testing was conducted utilizing those systems.

V. INDICATIONS FOR USE

Smart SPACE Shoulder 3D Positioner

Smart SPACE Shoulder System instrumentation consists of a patient-specific 3D positioner. It has been specially designed to assist in the intraoperative positioning of shoulder components used with total anatomic or reverse shoulder arthroplasty procedures using anatomic landmarks that are identifiable on patient-specific preoperative CT scans.

Smart SPACE Shoulder Cubit Guidance

Smart SPACE Shoulder Cubit Guidance consists of a patient-specific 3D mapper, single use instrumentation, and an intraoperative guidance software. They have been specially designed to assist in the intraoperative positioning of shoulder components used with total anatomic or reverse shoulder arthroplasty procedures using anatomic landmarks that are identifiable on patient-specific preoperative CT scans.

Smart SPACE Shoulder Planner software

Smart SPACE Shoulder Planner software is a medical device for surgeons composed of one software component. It is intended to be used as a pre-surgical planner for shoulder orthopedic surgery.

Smart SPACE Shoulder Planner software runs on standard personal and business computers running Microsoft Windows operating system.

The software supports DICOM standard to import the CT scan (Computed Tomography) images of the patient. Only CT scan modality can be loaded with the Smart SPACE Shoulder Planner software.

Smart SPACE Shoulder Planner software allows the surgeon to visualize, measure, reconstruct, annotate and edit anatomic data.

It allows the surgeon to design shoulder patient-specific instrumentation based on the pre-surgical plan.

The software leads to the generation of a surgical report along with a 3D file of the shoulder patient-specific instrumentation.

Smart SPACE Shoulder Planner software does not include any system to manufacture the shoulder patient-specific instrumentation.

Smart SPACE Shoulder Planner software is to be used for adult patients only and should not be used for diagnostic purposes.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- Indications for Use – The predicate and subject device have equivalent indications for use – both are indicated for use in total anatomic or reverse shoulder arthroplasty for planning of the procedure

and to assist in the accurate placement of surgical implants.

- Materials – The predicate and subject device have the same patient contacting material for the 3D Positioner/3D Mapper, which is PA2200. The Cubit sensor enclosures and adaptors to surgical instruments are made of Lustran 348 ABS, and the sensor power button is made of VersaFlex OM 1040x. Biocompatibility safety testing has been conducted on all materials and they were found to be biocompatible.
- Design – The predicate and subject device use the same software technology for surgical planning and final design of the 3D positioner/3D mapper. The subject device has the additional optional use of the Guidance system, which contains sensors (pods) to determine the correct positioning and alignment of the surgical instruments. This new design feature has been verified and validated and performs as well as the guide.
- Energy Source – The predicate and subject devices' software runs on computers. The 3D Positioner/3D Mapper and adaptors themselves do not have an energy source, but the subject device Cubit sensors that connect to the adaptors have lithium batteries. The energy source to the subject device has been safety and performance tested.
- Other Design Features – Both the predicate and the subject device have single use components. The predicate device components are provided non-sterile, and the subject device has both sterile and non-sterile components.
- Performance Testing – The subject and predicate device were primarily validated using non-clinical studies performed on cadaveric specimens. The subject device also underwent other testing, including electronics testing and usability engineering validation. The primary validation methods are the same and demonstrate compliance with the same recognized standards, demonstrating equivalence.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE REFERENCE DEVICE

The following characteristics were compared between the subject device and the reference device:

- Indications for Use – The subject device has indications for use that include both the planning software and the guidance system. The reference device has equivalent indications for assisting in the accurate placement of surgical implants as the subject device.
- Materials – The subject device uses PA2200 for the 3D Positioner/3D Mapper. The Cubit sensor enclosures and adaptors to surgical instruments are made of Lustran 348 ABS, and the reference device uses an unspecified plastic for its equivalent instrument guides. Biocompatibility safety testing has been conducted on all materials for both the subject device and the reference device and they were found to be biocompatible.
- Design – The subject and reference device both use wireless pods containing orientation sensors to support proper instrument alignment and accurate implant placement.
- Energy Source – The subject and reference device both have software that runs on tablets powered by lithium batteries, and the Cubit sensors of the subject device and the pods of the reference device run on lithium batteries.
- Other Design Features – The subject and the reference device have single use components which are provided both sterile and non-sterile.
- Performance Testing – The subject and reference device were primarily validated using non-clinical studies performed on cadaveric specimens, software verification and validation testing, electronics testing, and usability engineering. The primary validation methods are the same and demonstrate compliance with the same recognized standards, demonstrating substantial equivalence.

VII. SAFETY AND PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Sterilization & Shelf-life Testing

Sterilization, shelf life, and shipping validations were performed according to ISO 11135:2014, ISO 10993-7:2008, and ISO 11137-1:2018.

Biocompatibility Testing

Biocompatibility testing per ISO 10993-1:2018 was conducted to ensure the biocompatibility of the materials used in the 3D Positioner/3D Mapper, instrument adaptors, and Cubit sensors.

Electrical safety and electromagnetic compatibility (EMC)

Electrical Safety and Electromagnetic Compatibility testing was performed on the Cubit sensors of the subject device. Electrical safety of the Cubit sensor was tested to IEC 60601-1:2012, and electromagnetic compatibility of the Cubit Sensor was tested to IEC 60601-1-2:2014. Additional testing was conducted on the Lithium Power Cell per IEC 62133-2. Intentional/Unintentional Radiator testing was conducted per Title 47 of the CFR, Ch. 1 (03-01-2020 ed.). Ingress Testing was conducted per IEC 60529 Ed. 2.2(2013).

Software Verification and Validation Testing

Software Verification and Validation Testing was conducted in accordance with the requirements of ANSI AAMI IEC 62304:2006/A1:2015. The following FDA guidance documents were also followed: General Principles of Software Validation, Off-The-Shelf Software Used in Medical Devices, Cybersecurity for Networked Medical Devices Containing Off-the-Shelf Software, Postmarket Management of Cybersecurity in Medical Devices, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Usability Testing

Usability was validated in accordance with IEC 62366-1:2015 and 60601-1-6:2013.

Mechanical and Acoustic Testing

Mechanical and Acoustic testing was not applicable for this submission because the device is intended to be used as a temporary guide during a surgical procedure without critical mechanical performance testing requirements.

Animal Study

Animal performance testing was not required to demonstrate the safety and effectiveness of the device.

Clinical Studies

Clinical testing was not required to demonstrate the safety and effectiveness of the device.

Benchtop Performance

The Smart SPACE Shoulder System was validated through non-clinical studies performed on cadaveric specimens.

Post-operative implant placement was compared with the executed implant position captured by the Guidance System.

Testing has successfully demonstrated that the subject device performs as well as the predicate device with respect to version, inclination, and entry point.

VIII. CONCLUSIONS

The Smart SPACE Shoulder System (Subject Device System) described in this section has an equivalent intended use and the same fundamental scientific technology as the cleared predicate device, the Smart SPACE Shoulder System (K191247). The additional technological characteristic of the subject device is comparable to the reference device, the iASSIST Knee System (K192080).

Based on the performance data presented for the design differences between the subject device and predicate device, TechMah Medical concludes that the subject device is substantially equivalent to the predicate device.