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

December 28, 2020

Re: K202454
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, MBF
Dated: December 1, 2020
Received: December 1, 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)*
K202454

Device Name
Smart SPACE Shoulder System

Indications for Use *(Describe)*
Smart SPACE Shoulder 3D Positioners

Smart SPACE Shoulder System instrumentation consists of patient-specific 3D positioners. 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.

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; email: mary@fdaecopy.com
Contact Person:	Mohamed R. Mahfouz, Ph.D.
Date Prepared:	August 25, 2020

II. DEVICE

Name of Device:	Smart SPACE Shoulder System
Classification Name:	Shoulder Arthroplasty Implantation System Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Uncemented
Regulation:	21 CFR §888.3660 and 21 CFR §888.3670
Regulatory Class:	Class II
Product Classification Code:	QHE, KWS and MBF (The device is a planning system and surgical guides, primary code QHE, intended to be used with devices in product codes KWS and MBF)

III. PREDICATE DEVICE

Predicate Manufacturer:	TechMah Medical LLC
Predicate Trade Name:	SmartSPACE Shoulder System
Predicate 510(k):	K191247

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Smart SPACE Shoulder System consists of the Smart SPACE Shoulder Planner software and 3D Positioners which assist the user in planning reverse and anatomic total shoulder arthroplasty and gives the user the ability to translate the surgical plan intraoperatively using 3D positioners for glenoid K-wire placement and humeral head resection.

V. INDICATIONS FOR USE

Smart SPACE Shoulder 3D Positioners

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Smart SPACE Shoulder Planner software does not include any system to manufacture the shoulder patient-specific instrumentation.
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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.
- Materials – The predicate and subject device have the same patient contacting materials of PA 2200.
- Design – The predicate and subject device use the same software technology for the surgical planning and the final design of the 3D positioners.
- Energy Source – The predicate and subject devices' software runs on computers, the guides themselves do not have an energy source.
- Other Design Features – The subject device builds on already approved Smart SPACE shoulder system (K191247 / Predicate). Novel features in this device compared to predicate is the humerus 3D positioner which is a patient specific device that aids the surgeon in the resection of humeral head.
- Performance Testing – The subject and predicate device were primarily validated using non-clinical studies performed on cadaveric specimens. The primary validation method is the same and demonstrate compliance with the same recognized standards, demonstrating equivalence.

VII. PERFORMANCE DATA

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

Sterilization & Shelf-life Testing

Testing was performed to validate the end-user sterilization protocol of the subject device.

Biocompatibility Testing

Biocompatibility testing per ISO 10993-1 was conducted to ensure the biocompatibility of the materials used in the 3D positioners.

Electrical safety and electromagnetic compatibility (EMC)

Electrical Safety and Electromagnetic Compatibility testing is not applicable for these devices as there is not an energy source beyond that of the computer used with the planning software, which does not pose significant risk to users or patients.

Software Verification and Validation Testing

Software Verification and Validation Testing was conducted in accordance with the requirements of IEC 62304 and the following FDA guidance documents: 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.

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 safety and effectiveness of the device.

Clinical Studies

Clinical testing was required to demonstrate the safety and effectiveness of the device.

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

Benchtop Performance

Post-operative humeral head cut was compared with the executed humeral head cut using the Smart SPACE Humerus 3D Positioner.

Testing has successfully demonstrated that the subject device performs as well as existing traditional instrumentation currently used for executing the humeral head resection. The subject device translated the humeral head resection in a more accurate and precise manner compared to traditional instrumentation.

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 SmartSPACE Shoulder System (K191247). Based on the performance data presented for the subject device and predicate device, TechMah Medical concludes that the subject device is substantially equivalent to the predicate device.