TechMah Medical LLC
℅ Mary Vater
Regulatory Consultant
Medical Device Academy, Inc.
345 Lincoln Hill Rd.
SHREWSBURY VT 05738

Re: K191247
Trade/Device Name: SmartSPACE Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KWS, MBF, QHE
Dated: October 21, 2019
Received: October 21, 2019

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
Acting 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)*
K191247

Device Name
SmartSPACE Shoulder System

Indications for Use *(Describe)*
SmartSPACE Shoulder 3D Positioner

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

SmartSPACE Shoulder Planner software

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

K191247

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

Contact Person: Mohamed R. Mahfouz, Ph.D.
Date Prepared: May 7, 2019

II. DEVICE

Name of Device:	SmartSPACE Shoulder System
Classification Name:	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 in product code QHE, intended to be used with devices in product codes KWS and MBF)

III. PREDICATE DEVICE

Predicate Manufacturer:	Tornier SAS
Predicate Trade Name:	BLUEPRINT Patient Specific Instrumentation
Predicate 510(k):	K162800

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The SmartSPACE Shoulder System consists of the SmartSPACE Shoulder Planner software and a 3D positioner which assists the user in planning reverse and anatomic total shoulder arthroplasty and gives the user the ability to translate the surgical plan intraoperatively using a 3D positioner for glenoid K-wire placement.

V. INDICATIONS FOR USE

SmartSPACE Shoulder 3D Positioner

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

SmartSPACE Shoulder Planner software

SmartSPACE 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.

SmartSPACE 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 SmartSPACE Shoulder Planner software.
SmartSPACE 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.
SmartSPACE Shoulder Planner software does not include any system to manufacture the shoulder patient-specific instrumentation.
SmartSPACE Shoulder Planner software is to be used for adult patients only and should not be used for diagnostic purposes.

Compatible Implant Systems
The following Lima implants are supported by the SmartSPACE Shoulder System:

Device	**510(k)**
SMR Reverse – Metal Black	K113254
SMR Reverse – TT Metal Back	K133349
SMR Anatomic – Metal Back	K113254
SMR Anatomic – TT Metal Back	K133349
SMR Anatomic – 3 Pegs Glenoid	K130642, K153722
SMR Anatomic – Cemented Glenoid (single peg)	K100858
Hybrid Anatomic	K163397
Hybrid Reverse	K163397

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:

	SmartSPACE Shoulder System	BLUEPRINT Glenoid Guides and 3D Planning Software – K162800	Comments on Substantial Equivalence
Indications for Use	SmartSPACE Shoulder 3D Positioner SmartSPACE Shoulder System instrumentation consists of a patient-specific 3D positioner. It has been specially designed to assist in the intraoperative positioning of glenoid components used with total anatomic or reverse shoulder arthroplasty procedures using anatomic landmarks that are identifiable on patient-specific preoperative CT scans.	Hardware: The BLUEPRINT™ Glenoid Guides are patient-specific drill guides. They have been specially designed to assist in the intraoperative positioning of glenoid components used with total anatomic or reversed shoulder arthroplasty procedures using anatomic landmarks that are identifiable on patient-specific preoperative CT scans. Software:	Essentially identical indications for use. Therefore, Substantially Equivalent.

	SmartSPACE Shoulder Planner software SmartSPACE 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. SmartSPACE 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 SmartSPACE Shoulder Planner software. SmartSPACE 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. SmartSPACE Shoulder Planner software does not include any system to manufacture the shoulder patient-specific instrumentation. SmartSPACE Shoulder Planner software is to be used for adult patients only and should not be used for diagnostic purposes.	BLUEPRINT™ 3D Planning Software is a medical device for surgeon composed of one software component. It is intended to be used as a pre-surgical planner for shoulder orthopedic surgery. BLUEPRINT™ 3D Planning Software runs on standard personal and business computers running Microsoft Windows or Mac OS operating systems. The software supports DICOM standard to import the CT scan (Computed Tomography) images of the patient. Only CT scan modality can be loaded with BLUEPRINT™ 3D Planning Software. BLUEPRINT™ 3D Planning Software allows surgeon to visualize, measure, reconstruct, annotate and edit anatomic data. It allows surgeon to design glenoid patient-specific guides based on the pre-surgical plan. The software leads to the generation of a surgery report along with a 3D file of the glenoid patient-specific guide. BLUEPRINT™ 3D Planning Software does not include any system to manufacture the glenoid patient-specific guide. BLUEPRINT™ 3D Planning Software is to be used for adult patients only and should not be used for diagnostic purpose.	
Materials	Medical grade polyamide PA2200	The commercially available BLUEPRINT Glenoid Guides are manufactured from medical grade polyamide (PA 2200) or titanium (Ti6Al4V).	The main patient contacting material of the guides is the same for the predicate and subject device.
Design	The SmartSPACE Shoulder System consists of the following functional elements: • SmartSPACE Shoulder Planner software • SmartSPACE Shoulder 3D Positioner	Surgical Guides and Planning Software	Both subject and predicate devices have glenoid guides and presurgical planning software. Therefore, they are substantially equivalent.

Energy Source	Guides (3D positioners) have no energy source. Software Only, used on user's computer.	Guides have no energy source. Software Only, used on user's computer.	Substantially Equivalent
Other Features	Single-Use Non-Sterile	Single-Use Non-Sterile	Substantially Equivalent
Performance Testing	The SmartSPACE Shoulder System was validated through non-clinical studies performed on cadaveric specimen or performed by using patients' data including: – Glenoid Version and Inclination Angle Validation Test - The version and inclination angle between reference method and the software calculation should be compliant. – Patient-Specific Guiding Wire Test - Version angle error, inclination angle error and entry point error should be compliant. – Segmentation Accuracy Test - Mean Distance Error in the surgical zone between 3D reconstruction and the reference reconstruction should be compliant. – Cadaver Validation Study - Pre-operative surgical plan compared to post-operative implant position should be compliant.	BLUPRINT Patient Specific Instrumentation was validated through non-clinical studies performed on cadaveric specimen or performed by using patients' data including: – Seating Validation Test – Reaming Validation Test – Orientation and Direction Angles Validation Test – Glenoid Version and Inclination Angle Validation Test – Humeral Head Subluxation and Direction Measure – Patient Specific Guiding Wire Test – Segmentation Accuracy Test – Clinical Case Studies	The primary validation method was the same. They both required use of the software to produce guides and then use of the guides on cadaveric specimens. For the subject device, the seating and reaming can be conducted using the coverage map within the software, so this feature was validated through software testing. The subject device does not require subluxation measurement. The subject device also underwent Human Factors Validation testing to ensure users were able to use the software and guides as intended with the available instructions for use and training videos.

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.

Software Verification and Validation Testing

Software Verification and Validation Testing was conducted in accordance with the requirements of IEC 62304. The subject device also underwent Human Factors Validation testing to ensure users were able to use the software and guide as intended with the available instructions for use and training videos.

Benchtop Performance

The SmartSPACE Shoulder System was validated through non-clinical studies performed on cadaveric specimen or performed by using patients' data including:

- Glenoid Version and Inclination Angle Validation Test - The version and inclination angle between reference method and the software calculation should be compliant.
- Patient-Specific Guiding Wire Test - Version angle error, inclination angle error and entry point error should be compliant.
- Segmentation Accuracy Test - Mean Distance Error in the surgical zone between 3D reconstruction and the reference reconstruction should be compliant.
- Cadaver Validation Study - Pre-operative surgical plan compared to post-operative implant position should be compliant.

VIII. CONCLUSIONS

The SmartSPACE Shoulder System (Subject Device System) described in this section has an equivalent intended use and the same fundamental scientific technology as the cleared BLUEPRINT Patient Specific Instrumentation (K162800). 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.