October 2, 2023

TechMah CMF
Lyndsay Bowers
VP Quality
2240 Sutherland Ave, Suite 2
Knoxville, Tennessee 37919

Re: K231520
Trade/Device Name: tmCMF Solution
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZJ, LLZ
Dated: September 11, 2023
Received: September 11, 2023

Dear Lyndsay Bowers:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K231520

Device Name
tmCMF Solution

Indications for Use *(Describe)*
The tmCMF Solution is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT-based system. The input data file is processed by the tmCMF Solution, and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, surgical guides, and dental splints for use in maxillofacial and mandibular surgery. The surgical guides and dental splints are intended to be used for the maxillofacial and mandibular bone in maxillofacial and mandibular surgery. The tmCMF Solution is also intended as a preoperative software tool for simulating/evaluating surgical treatment options.

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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510(k) SUMMARY

K231520

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

Date Prepared: October 2, 2023

I. CONTACT DETAILS

Applicant Name:	TechMah CMF
Applicant Contact Telephone:	+1.865.200.4376
Applicant Contact:	Dr. Mohamed Mahfouz
Applicant Contact Email:	mmahfouz@tmcmf.com
Applicant Address:	2240 Sutherland Avenue, Suite 2 Knoxville, TN 37919 United States
Correspondent Name:	TechMah CMF
Correspondent Contact Telephone:	+1.410.258.2770
Correspondent Contact:	Mrs. Lyndsay Bowers
Correspondent Contact Email:	lbowers@tmcmf.com
Correspondent Address:	2240 Sutherland Avenue, Suite 2 Knoxville, TN 37919 United States

II. DEVICE NAME

Device Trade Name:	tmCMF Solution
Device Common Name:	Surgical Guide and Surgical Planning Software
Classification Name:	Bone Cutting Instrument And Accessories
Regulation Number:	21 CFR §872.4120
Product Code:	DZJ
Subsequent Product Code:	LLZ

III. LEGALLY MARKETED PREDICATE DEVICES

Predicate Number:	K192282
Predicate Trade Name:	MedCAD AccuPlan System
Product Code:	DZJ

IV. LEGALLY MARKETED REFERENCE DEVICES

Predicate Number:	K103136
Predicate Trade Name:	SurgiCase mandible/maxillofacial guides
Product Code:	JEY
Predicate Number:	K170419
Predicate Trade Name:	SurgiCase Viewer
Product Code:	LLZ
Predicate Number:	K210347
Predicate Trade Name:	VSP System
Product Code:	DZJ, LLZ
Predicate Number:	K120956
Predicate Trade Name:	VSP System
Product Code:	DZJ, LLZ

V. DEVICE DESCRIPTION SUMMARY

The TechMah CMF (tmCMF) Solution is a family of personalized product solutions for trauma and reconstruction procedures in the mandible and midface. The solution is comprised of Surgeon Review Tool (SRT) software, and maxillofacial and mandibular surgical instruments (surgical guides, anatomical models, and dental splints). The surgical instruments are patient-specific devices and are designed utilizing CT and dental scan patient image data.

Surgical guides are patient-specific devices or templates that are based on pre-operative software planning and are designed to fit a specific patient. These guides are used to assist a surgeon in transferring the pre-operative plan to the surgery by guiding the marking of bone for plate fixation screws and the position of the osteotomy marking slots. Surgical guides are available for treatment (maxilla and mandible) and harvesting (fibula, iliac crest, and scapula). Guides can be used in conjunction with anatomical models to verify anatomical positioning and fit.

Anatomical models are patient-specific models that are based on pre-operative anatomy and surgical planning specific to a patient. These models are used to assist a surgeon in transferring the pre-operative plan to the surgery by representing pre-operative, intra-operative, and post-operative anatomical models as guidance. Anatomical models are available for treatment (maxilla and mandible), and harvesting (fibula, iliac crest, and scapula) anatomy. Anatomical models can be used to check

guide fit.

Dental splints are patient-specific devices or templates that are based on pre-operative software surgical planning and are designed to fit a specific patient. Dental splints are available as single splint desired occlusions or combined splint-in-splint option. These templates are used to assist a surgeon in transferring the pre-operative plan to the surgery by guiding the dental alignment of bone and teeth.

The Surgeon Review Tool (SRT) software is used by surgeons for the review and approval of surgical plans and surgical instrument designs. The SRT software is accessed through a web interface from a surgeon's device.

VI. INTENDED USE/INDICATIONS FOR USE

The tmCMF Solution is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT-based system. The input data file is processed by the tmCMF Solution, and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, surgical guides, and dental splints for use in maxillofacial and mandibular surgery. The surgical guides and dental splints are intended to be used for the maxillofacial and mandibular bone in maxillofacial and mandibular surgery. The tmCMF Solution is also intended as a preoperative software tool for simulating/evaluating surgical treatment options.

VII. SUBSTANTIAL EQUIVALENCE COMPARISON

	tmCMF Solution (Subject device)	MedCAD® AccuPlan® System (Predicate device) K192282	SurgiCase Viewer (K170419) Reference Device	SurgiCase mandible/maxillofacial guides (K103136) Reference Device	VSP System (Reference device) K210347
Indication for Use	The tmCMF Solution is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT-based system. The input data file is processed by the tmCMF Solution, and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, surgical guides, and dental splints for use in maxillofacial and mandibular surgery. The surgical guides and dental splints are intended to be used for the maxillofacial and mandibular bone in maxillofacial and mandibular surgery. The tmCMF Solution is also intended as a preoperative software tool for simulating/evaluating surgical treatment options.	The MedCAD® AccuPlan® System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the MedCAD® AccuPlan® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, surgical guides, and dental splints for use in maxillofacial surgery. The surgical guides and dental splints are intended to be used for the maxillofacial bone in maxillofacial surgery. The MedCAD® AccuPlan® System is also intended as a preoperative software tool for simulating / evaluating surgical treatment options.	SurgiCase Viewer is intended to be used as a software interface to assist in visualization and communication of treatment options.	SurgiCase Guides are intended to be used as surgical tools to transfer a pre-operative plan to the surgery. The devices are intended to guide the marking of bone and/or guide surgical instruments in mandibular and maxillofacial surgical procedures	The VSP® System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the VSP® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, templates, and surgical guides for use in maxillofacial surgery.
Preoperative software	Yes	Yes	Yes	Yes	Image transformation into 3D models, Computer Aided Design, Surgical planning / simulation
Additive manufacturing of splint, guides, and models	Yes	Yes	Unknown	Yes	3D Printing to produce physical output devices
Data Inputs	Images from medical scanners	Images from medical scanners	Images from medical scanners	Images from medical scanners	DICOM file from Medical Scanner (CT, CBCT), patient contoured and standard implant .STL files; input from Physician

	tmCMF Solution (Subject device)	**MedCAD® AccuPlan® System (Predicate device) K192282**	**SurgiCase Viewer (K170419) Reference Device**	**SurgiCase mandible/maxillofacial guides (K103136) Reference Device**	**VSP System (Reference device) K210347**
Data Outputs	Output for dental splints, surgical guides, and anatomical models	Output for dental splints, surgical guides, and anatomical models	Approved plans and designs	Output for dental splints, surgical guides, and anatomical models	Output for dental splints, surgical guides, and anatomical models
Physical Outputs	Dental splints, surgical guide, anatomical models, and patient-specific case reports	Dental splints, surgical guide, anatomical models, and patient-specific case reports	Unknown	Dental splints, surgical guide,	Dental splints, surgical guide, anatomical models
Sterilization	Device is provided non-sterile and is steam sterilized by the end-user	Device is provided non-sterile and is steam sterilized by the end-user	Unknown	Device is provided non-sterile and is steam sterilized by the end-user	Steam sterilization
Manufacturing Method	Additive Manufacturing	Additive Manufacturing	Unknown	Additive Manufacturing	Additive Manufacturing
Web Interface	Yes	Unknown	Yes	No	Unknown
2D Image Display Axial Sagittal Coronal	Yes	Yes	Yes	Yes	Yes
3D Visualization	Yes	Yes	Yes	Yes	Yes
Installation Required	No	Unknown	No	Yes	Unknown
Physician Interaction with Planning and Physician Model / Guide Approval	Yes	Yes	Yes	Yes	Yes
Single Use	Yes	Yes	NA	Yes	Yes

VIII. INDICATIONS FOR USE COMPARISON

The tmCMF Solution has equivalent indication for use as its predicate device. The primary indication is to utilize pre-operative imaging data to perform surgical case planning and create patient-specific instrumentation to transfer the pre-operative plan on the patient in the operating room.

Differences

- The predicate specifically refers to maxillofacial surgery, whereas the subject device covers both maxillofacial and mandibular surgeries, which is equivalent to the reference device (K103136).
- The predicate device does not include graft harvesting surgical guides, whereas the subject does. However, the predicate device (K120956) used by the current predicate (K192282) also included harvesting surgical guides, which is equivalent to the reference device (K210347)
- The predicate device has a limited contact for the splint whereas the subject device has a prolonged contact for splints to allow for post-op usage of up to 30 days. However, the predicate device (K120956) used by the current predicate (K192282) also has a prolonged contact for splints to allow for post-op usage of up to 30 days, which is equivalent to the reference device (K210347).

IX. TECHNOLOGICAL COMPARISON (WITH PREDICATE DEVICE)

Similarities to Predicate

The tmCMF Solution has the same intended use and similar technological characteristics as the identified predicate device. The system employs similar fundamental technologies as the identified predicates including input case data, manipulation, and surgical planning. The principles of operation and technological characteristics are either identical or substantially equivalent to the predicate. The system has similar technological characteristics including:

- System inputs: images from medical scanners (ex: CT), dental models, and/or implant files (.STL)
- System outputs: physical and/ or digital outputs such as patient-specific anatomical models, guides, and splints
- Materials: biocompatible polymers
- Sterility assurance level of 1x10-6

The intended use of the subject device and the predicate both provide tools and accessories (software for image manipulation, anatomical models, splints, and guides) for use in reconstructive surgery. Additionally, both the subject and the predicate device are intended to be used by trained personnel with active support

from the surgeon.

Differences to Predicate

- The predicate specifically refers to maxillofacial surgery, whereas the subject device covers both maxillofacial and mandibular surgeries.
- The predicate device does not include graft harvesting surgical guides, whereas the subject does. However, the predicate device (K120956) used by the current predicate (K192282) also included harvesting surgical guides.
- The predicate device has a limited contact for the splint whereas the subject device has a prolonged contact for splints to allow for post-op usage of up to 30 days. However, the predicate device (K120956) used by the current predicate (K192282) also has a prolonged contact for splints to allow for post-op usage of up to 30 days.

X. TECHNOLOGICAL COMPARISON (WITH REFERENCE DEVICES)

Reference device K170419:

- The reference device served as a technologically equivalent device for the Surgeon Review Tool (SRT).

Reference device K103136:

- This reference device was used to establish performance equivalence data.

Reference devices K210347 and K120956:

- The reference devices served as the basis for establishing equivalence on physical product features and offerings, product material compositions and their manufacturing processes. The reference devices encompass anatomical models, surgical guides, and dental splints, with the subject device utilizing similar product features and identical materials to ensure a state of equivalence.

The addition of the reference device comparison presents another substantially equivalent device with identical physical outputs, materials, and manufacturing processes.

XI. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY

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

Cleaning

Testing was performed to validate the end-user cleaning protocol of the subject

device per the FDA Guidance Document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” and AAMI TIR 30.

Sterilization

Testing was performed to validate the end-user sterilization protocol of the subject device per ISO 17665-1, ISO 17665-2, and ANSI/AAMI ST79.

Biocompatibility

Biocompatibility assessment per the FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” and biocompatibility testing per ISO 10993-1:2018 for its contact classification was conducted to ensure the biocompatibility of the materials and manufacturing process used in the tmCMF surgical instruments.

Software Verification and Validation

Software Verification and Validation Testing was conducted in accordance with the requirements of 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 Device Software Functions.

Usability

Usability was validated in accordance with IEC 62366-1:2020.

Benchtop Performance

Benchtop performance testing was performed to demonstrate the performance of the tmCMF Solution and substantial equivalence with the predicate device. The testing aligns with the test strategy and performance metrics used by the predicate.

Hardware Performance Verification	Testing demonstrated that the surgical guide and dental splint meets the predetermined acceptance criteria.
Cadaveric Benchtop Performance Testing	Comparison of pre-operative surgical plan to post-operative CT measurements. Results passed the predetermined acceptance criteria, indicating substantial equivalence.
Hardware Integrity test Verification	Testing demonstrated that the instruments meet the predetermined acceptance criteria.
Hardware Verification Inspection and Analysis	Testing demonstrated that instruments' implementation is compliant with the acceptance criteria.

Surgical Case Verification	Testing demonstrated that the surgical case reports are compliant with acceptance criteria.
System Validation	Testing demonstrated that the system has met user needs and is compliant with acceptance criteria.

XII. CONCLUSION

The tmCMF Solution has the same intended use as the predicate device and similar technological characteristics as the predicate and reference devices. Therefore, the subject device is substantially equivalent.