July 11, 2024

TechMah CMF
Lyndsay Bowers
VP Quality
2099 Thunderhead Road, Suite 302
Knoxville, Tennessee 37922

Re: K233874
Trade/Device Name: tmCMF Solution
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZJ, LLZ
Dated: June 21, 2024
Received: June 21, 2024

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,

Sherrill Lathrop Blitzer

for Andrew I. Steen
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233874

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 manufacturing portion of the system that produces physical outputs, including anatomical models, surgical guides, dental splints, and implants for use in maxillofacial, midface, and mandibular surgery. Implants are intended for bone fixation and reconstruction, restoration of bone defects, and intended to provide continuity in regions where the bone is missing and/or to augment the bone by means of an onlay device in the maxillofacial skeleton, midface, mandible, and chin in adolescents (greater than 12 to 21 years of age) and adults. The tmCMF Solution is also intended as a preoperative software tool for simulating/ evaluating virtual 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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K233874
510(k) SUMMARY

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

Date Prepared: July 8, 2024

I. CONTACT DETAILS

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Correspondent Contact:	Mrs. Lyndsay Bowers
Correspondent Contact Email:	lbowers@tmcmf.com
Correspondent Address:	2099 Thunderhead Rd, Suite 302 Knoxville, TN 37922 United States

II. DEVICE NAME

Device Trade Name:	tmCMF Solution
Regulation Name:	Dental
Classification Name:	Plate, Bone
Regulation Number:	21 CFR §872.4120
Product Code:	JEY
Subsequent Product Code:	DZJ, LLZ

III. LEGALLY MARKETED PREDICATE DEVICES

Predicate Number:	K231520
Predicate Trade Name:	tmCMF Solution
Product Code:	DZJ & LLZ
Use:	Primary Predicate

Predicate Number: K173039
Predicate Trade Name: TruMatch CMF Titanium 3D Printed Implant
Product Code: JEY
Use: Secondary Predicate

Predicate Number: K170272
Predicate Trade Name: TruMatch CMF Titanium 3D Printed Implant System
Product Code: JEY
Use: Secondary Predicate

IV. LEGALLY MARKETED REFERENCE DEVICES

Predicate Number: K063790
Predicate Trade Name: SYNTHES MATRIXMANDIBLE PLATE AND SCREW SYSTEM
Product Code: JEY

Predicate Number: K210731
Predicate Trade Name: KLS Martin Individual Patient Solutions
Product Code: JEY

Predicate Number: K213684
Predicate Trade Name: SurgiCase Viewer
Product Code: LLZ

Predicate Number: K080331
Predicate Trade Name: Synthes Craniofacial Plate and Screw System
Product Code: JEY

Predicate Number: K050608
Predicate Trade Name: Synthes (USA) Craniofacial Plate and Screw System
Product Code: JEY

Predicate Number: K083388
Predicate Trade Name: SYNTHES MATRIXORTHOGNATHIS FIXATION SYSTEM
Product Code: JEY

V. DEVICE DESCRIPTION SUMMARY

TechMah CMF (tmCMF) Solution is a family of personalized product solutions for Reconstructive, Orthognathic, Trauma, and Augmentation procedures in the mandible and midface (including orbital floor, medial and lateral orbital walls). The solution is comprised of Surgeon Review Tool (SRT) software and maxillofacial and mandibular surgical instruments (surgical guides, anatomical models, and dental splints) and implants. The surgical instruments and implants are patient-specific devices and are designed utilizing CT and dental scan patient image data.

Surgical guides are patient-specific devices or templates based on pre-operative software planning 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/drilling of bone for plate fixation screws and the position of the osteotomy marking/cutting slots. Guides can be used in conjunction with anatomical models to verify anatomical positioning and fit. Surgical guides can be used with either tmCMF Solution patient-specific implants or compatible off-the-shelf DePuy Synthes implants.

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 can be used to check guide fit and facilitate the pre-bending of a non-patient-specific off-the-shelf plate.

Dental splints are patient-specific devices or templates based on pre-operative software planning designed to fit a specific patient. 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.

Implants are patient-specific devices that are based on pre-operative software planning designed to fit a specific patient. These implants are integral components for CMF (craniomaxillofacial) procedures, facilitating bone repositioning, fixation, reconstruction, and the restoration of bone defects. They are designed according to the pre-operative surgical plan to ensure continuity in regions where bone is absent and to provide structural integrity to the maxillofacial skeletal components, midface, mandible, and chin. This could include stabilizing fractured or intraoperatively cut bone, fixating harvested graft segments, or augmenting bone defects. Implants can be used in conjunction with surgical guides and anatomical models to assist with anatomical positioning and fit.

The Surgeon Review Tool (SRT) software is used by surgeons for the review of surgical plans, surgical instruments, and implant designs. The SRT software is accessed through a web interface.

tmCMF Solution supports the following maxillofacial, midface (including orbital floor, lateral and medial orbital wall), and mandibular surgical procedures:

- Reconstructive
- Orthognathic
- Trauma
- Augmentation

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 manufacturing portion of the system that produces physical outputs, including anatomical models, surgical guides, dental splints, and implants for use in maxillofacial, midface, and mandibular surgery. Implants are intended for bone fixation and reconstruction, restoration of bone defects, and intended to provide continuity in regions where the bone is missing and/or to augment the bone by means of an onlay device in the maxillofacial skeleton, midface, mandible, and chin in adolescents (greater than 12 to 21 years of age) and adults. The tmCMF Solution is also intended as a preoperative software tool for simulating/evaluating virtual surgical treatment options.

VII. SUBSTANTIAL EQUIVALENCE COMPARISON

Comparison of the Subject Device to the Primary Predicate Device

	tmCMF Solution (subject device)	tmCMF Solution (Primary predicate device K231520)	Comment on Substantial Equivalence
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 manufacturing portion of the system that produces physical outputs, including anatomical models, surgical guides, dental splints, and implants for use in maxillofacial, midface, and mandibular surgery. Implants are intended for bone fixation and reconstruction, restoration of bone defects, and intended to provide continuity in regions where the bone is missing and/or to augment the bone by means of an onlay device in the maxillofacial skeleton, midface, mandible, and chin in adolescents (greater than 12 to 21 years of age) and adults. The tmCMF Solution is also intended as a preoperative software tool for simulating/evaluating virtual surgical treatment options.	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 subject device is a solution that includes software and patient-specific instruments (anatomical models, surgical guides, splints), and patient-specific implants. The subject device is an update to its primary predicate device (K231520) to include patient-specific implants. The subject device and the primary predicate device share identical indications for use for the software and patient-specific instrumentation.

	tmCMF Solution (subject device)	tmCMF Solution (Primary predicate device K231520)	Comment on Substantial Equivalence
Data Inputs	Images from medical scanners	Images from medical scanners	The subject device is an update to the primary predicate device K231520, with no change in inputs from the predicate device. The data inputs are substantially equivalent.
Data Outputs	Output for dental splints, surgical guides, anatomical models, and implants	Output for dental splints, surgical guides, and anatomical models	The subject device outputs for polyamide (PA) surgical guides and anatomical models are identical to the primary predicate device K231520. The subject device introduces two additional outputs for Ti surgical guides and implants which are equivalent to the secondary predicate devices K173039 and K170272. Subject device and primary predicate device outputs for dental splints are identical with the exception that the subject device introduces an optional titanium (Ti) palatal insert for dental splints, which is equivalent to the reference device K210731.

	tmCMF Solution (subject device)	tmCMF Solution (Primary predicate device K231520)	Comment on Substantial Equivalence
Physical Outputs	Dental splints, PA surgical guides, Ti surgical guides, anatomical models, implants, and patient-specific case reports	Dental splints, surgical guides, anatomical models, and patient-specific case reports	The subject device's physical outputs for surgical guides (PA), and anatomical models are identical to the primary predicate device K231520. The subject device includes two additional physical outputs for surgical guides (titanium) and implants, which are equivalent to the secondary predicate devices K173039 and K170272. The subject device and primary predicate device K231520 physical outputs for dental splints are identical with the exception that the subject device introduces an optional palatal insert (titanium) for dental splints, which is equivalent to the reference device K210731.
Sterilization	Steam sterilization for both terminal and reprocessing. Sterility assurance level of 1x10-6	Steam sterilization. Sterility assurance level of 1x10-6	The subject device sterilization method for both end sterilization and terminal sterilization are equivalent to the predicate device.
Packaging	Non-Sterile Sterile	Non-Sterile	The subject device offers the same identical non-sterile packaging as the predicate device. The subject device adds sterile packaging which was not present in the primary predicate device.

	tmCMF Solution (subject device)	tmCMF Solution (Primary predicate device K231520)	Comment on Substantial Equivalence
Patient Contact	Surgical guides: Surface Contacting – Tissue / Bone Limited (< 24 hours) Dental splints: Surface Contacting – Mucosal Membrane Prolonged (< 30 days) Implants: Tissue/Bone contacts for Long-term implantation, as directed by HCP	Surgical guides: Surface Contacting – Tissue / Bone Limited (< 24 hours) Dental splints: Surface Contacting – Mucosal Membrane Prolonged (< 30 days)	The subject device surgical guides' and dental splints' patient contacting surfaces and duration are identical to the primary predicate device K231520. The subject device differs from the predicate device in that it offers implants with long-term tissue/bone implantation as directed by HCP.
Anatomic Areas of Use	Mandible, Midface (including orbit)	Mandible, Midface	The subject device and primary predicate device contact areas are mandible and midface. The subject device adds support for orbit which is part of the midface.
Patient Population	Adolescents (12 to 21 years) and adults	Adolescents (12 to 21 years) and adults	The target patient population for both subject and primary predicate device is identical.
Web Interface	Yes	Yes	The subject device is an update to the primary predicate device K231520, it utilizes the same identical web interface.
2D Image Display Axial Sagittal Coronal	Yes	Yes	Both the subject device and the primary predicate device K231520 display 2D images and are substantially equivalent.
3D Visualization	Yes	Yes	The subject and the primary predicate device K231520 have 3D visualization and are substantially equivalent.

	tmCMF Solution (subject device)	tmCMF Solution (Primary predicate device K231520)	Comment on Substantial Equivalence
Preoperative software	Yes	Yes	The subject device is an update to the primary predicate device K231520. The subject device uses pre-operative software in the same manner as the primary predicate device and is substantially equivalent.
Installation Required	No	No	The subject and primary predicate device K231520 do not require installation and are substantially equivalent.
Physician Interaction with Planning and Design Review	Yes	Yes	The physician can interact with planning and hardware designs for both the subject device and the primary predicate device K231520; thus, they are substantially equivalent.
Single-Use	Yes	Yes	The subject and the primary predicate device K231520 are single-use and are substantially equivalent
Implant Visualization	Yes	No	The subject device is an update to the primary predicate device K231520, with an added ability to visualize implants on CT images. This functionality is equivalent to the reference device K213684.

Comparison of Subject Device to Secondary Predicate Device for Ti Hardware

	tmCMF Solution (Subject device)	TruMatch CMF Titanium 3D Printed Implant System (K173039)	TruMatch CMF Titanium 3D Printed Implant System (K170272)	Comment on Substantial Equivalence
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 manufacturing portion of the system that produces physical outputs, including anatomical models, surgical guides, dental splints, and implants for use in maxillofacial, midface, and mandibular surgery. **Implants are intended for bone fixation and reconstruction, restoration of bone defects, and intended to provide continuity in regions where the bone is missing and/or to**	The TruMatch CMF Titanium 3D Printed Implant is a patient specific implant and **is intended for bone fixation and reconstruction, restoration of bone defects and intended to provide continuity in regions where the bone is missing and/or to augment the bone by means of an onlay device in the maxillofacial skeleton, midface and chin.**	The TruMatch CMF Titanium 3D Printed Implant **System is intended for bone repositioning, fixation and reconstruction of the maxillofacial skeleton, midface, mandible and chin in adolescents (greater than 12 to 21 years of age) and adults.** Specific indications for use: • Orthognathic surgery • Reconstructive mandible and maxillofacial surgery • mandible and maxillofacial trauma surgery	The subject device is a solution that includes software and patient-specific instruments (anatomical models, surgical guides, dental splints) and patient-specific implants. Both secondary predicate devices' indication for use is a subset of the subject device as both are Ti implants and surgical guides hardware with no software or plastic instruments. The subject device and the secondary predicate device (K173039) have an equivalent indication for use: bone fixation, reconstruction, and bone augmentation/enhancement in the mandible, midface, and chin. The subject device and the secondary predicate device (K170272) have equivalent indication for use including target patient population.

	tmCMF Solution (Subject device)	TruMatch CMF Titanium 3D Printed Implant System (K173039)	TruMatch CMF Titanium 3D Printed Implant System (K170272)	Comment on Substantial Equivalence
	augment the bone by means of an onlay device in the maxillofacial skeleton, midface, mandible, and chin in adolescents (greater than 12 to 21 years of age) and adults. The tmCMF Solution is also intended as a preoperative software tool for simulating/evaluating virtual surgical treatment options.			
Intended Use	Bone fixation and reconstruction, restoration of bone defects, and intended to provide continuity in regions where the bone is missing and/or to augment the bone by means of an onlay device in the maxillofacial skeleton, midface, mandible, and chin	Bone fixation and reconstruction, restoration of bone defects and intended to provide continuity in regions where the bone is missing and/or to augment the bone by means of an onlay device in the maxillofacial skeleton, midface, and chin	Bone repositioning, fixation, and reconstruction of the maxillofacial skeleton, midface, mandible, and chin	The subject and secondary predicate device (K173039) have the same intended use: bone fixation, reconstruction, and bone augmentation/ enhancement in the mandible, midface, and chin. The subject and secondary predicate devices (K170272) have the same intended use: bone fixation and reconstruction in the mandible, midface, and chin.

	tmCMF Solution (Subject device)	TruMatch CMF Titanium 3D Printed Implant System (K173039)	TruMatch CMF Titanium 3D Printed Implant System (K170272)	Comment on Substantial Equivalence
Intended Anatomical Regions	Mandible, Midface (including orbital floor, medial & lateral orbital walls)	Mandible, Midface (including orbital floor, medial & lateral orbital walls)	Mandible, Midface (including orbital floor, medial & lateral orbital walls)	The subject and secondary predicate devices (K173039, K170272) are used in the same anatomical regions.
Patient Population	Adolescents (12 to 21 years) and adults	Adolescents (12 to 21 years) and adults	Adolescents (12 to 21 years) and adults	The target patient population for both subject and secondary predicate devices are identical.
Sterilization	Steam Sterilization for both terminal and reprocessing. Sterility assurance level of $1x10^{-6}$	Steam Sterilization Sterility assurance level of $1x10^{-6}$	Steam sterilization Sterility assurance level of $1x10^{-6}$	The subject device sterilization method is equivalent to the secondary predicate devices (K173039, K170272). Sterilization effectiveness is demonstrated by testing and analysis.
Packaging	Non-Sterile Sterile	Non-Sterile	Non-Sterile	Subject device offers both sterile and non-sterile packaging, whereas the secondary predicate devices offer non-sterile packaging. Packaging integrity and stability is demonstrated by testing and analysis.

	tmCMF Solution (Subject device)	TruMatch CMF Titanium 3D Printed Implant System (K173039)	TruMatch CMF Titanium 3D Printed Implant System (K170272)	Comment on Substantial Equivalence
Patient Contact	Ti surgical guides: Surface Contacting – Tissue / Bone Limited (< 24 hours) Implants: Tissue/Bone contacts for Long-term implantation, as directed by HCP	Ti surgical guides: Surface Contacting – Tissue / Bone Limited (< 24 hours) Implants: Tissue/Bone contacts for Long-term implantation, as directed by HCP	Ti surgical guides: Surface Contacting – Tissue / Bone Limited (< 24 hours) Implants: Tissue/Bone contacts for Long-term implantation, as directed by HCP	The subject and secondary predicate devices (K173039, K170727) have equivalent patient contact tissue types and duration.
Single-Use	Yes	Yes	Yes	The subject device and secondary predicate devices are single-use and are substantially equivalent.
Ti Surgical Guides Use	Cutting/Drilling	Cutting/Drilling	Cutting/Drilling	The subject and the secondary predicate devices (K173039, K170272) have the same use for cutting and drilling of bone.
Implants made patient-specific	Yes	Yes	Yes	Implants for the subject and secondary predicate devices (K173039, K170727) are made patient-specific, manufactured from patient CT scan data.

	tmCMF Solution (Subject device)	TruMatch CMF Titanium 3D Printed Implant System (K173039)	TruMatch CMF Titanium 3D Printed Implant System (K170272)	Comment on Substantial Equivalence
Device compatibility	Mandible: DePuy Synthes MatrixMANDIBLE Midface, orbital: DePuy Synthes MatrixMIDFACE Orthognathic DePuy Synthes MatrixORTHOGNATHIC	Mandible: DePuy Synthes MatrixMANDIBLE Midface, orbital: DePuy Synthes MatrixMIDFACE	Mandible: DePuy Synthes MatrixMANDIBLE Midface, orbital: DePuy Synthes MatrixMIDFACE Orthognathic DePuy Synthes MatrixORTHOGNATHIC	The subject device and the secondary predicate devices (K173039, K170272) have equivalent device compatibility.
Screw Style	Locking Non-Locking	Non-Locking	Non-Locking	The subject device and the secondary predicate device (K173039, K170272) offer non-locking screws. The subject device and the reference device K063790 offer locking screws.
Anodization	Yes	Yes	Yes	The subject device is equivalent to both secondary predicate devices (K173039, K170272) in offering anodization.

	tmCMF Solution (Subject device)	TruMatch CMF Titanium 3D Printed Implant System (K173039)	TruMatch CMF Titanium 3D Printed Implant System (K170272)	Comment on Substantial Equivalence

Plates Dimensional Ranges	Reconstruction (Midface)
	• Length: 20-294 mm
	• Width: 4.0 mm
	
	Reconstruction (Mandibular)
	• Length: 20-294 mm
	• Width: 4.0-7.5 mm
	
	Orthognathic
	• 20 mm maximum advancement
	• Maxillary
	  ○ Width: 2.4 – 4.0 mm
	• Mandibular
	  ○ Single strut width: 4.5 – 8.0 mm
	  ○ Double strut width: 2.7 – 4.5 mm (each strut)
	• Genioplasty
	  ○ Width: 2.4 – 4.0 mm
	
	Orbital
	• Length: 5.5 – 4 mm
		N/A	Reconstruction (Midface)
			• Length: 20-294 mm
			• Width: 4.0 mm
			
			Reconstruction (Mandibular)
			• Length: 20-294 mm
			• Width: 4.0 mm
			
			Orthognathic
			• 20 mm maximum advancement
			• Maxillary
			  ○ Width: 2.4 – 4.0 mm
			• Mandibular
			  ○ Single strut width: 4.5 – 8.0 mm
			  ○ Double strut width: 2.7 – 4.5 mm (each strut)
			• Genioplasty
			  ○ Width: 2.4 – 4.0 mm
			
			Orbital
			• Length: 5.5 – 45 mm
				The subject and the secondary predicate device K170272 have equivalent ranges of plate length and width with the exception that the subject device offers a wider mandible reconstruction plate that is within the range of reference device K063790.

Profile Implants Range of Lengths	Reconstruction (Midface, Mandibular) • 10 – 294 mm	Reconstruction (Midface, Mandibular) • 10 – 294 mm	N/A	The subject device and the secondary predicate device K173039 have equivalent ranges of implant length.

	tmCMF Solution (Subject device)	TruMatch CMF Titanium 3D Printed Implant System (K173039)	TruMatch CMF Titanium 3D Printed Implant System (K170272)	Comment on Substantial Equivalence
Plate Thickness	Mandible reconstruction • 1.0 – 3.0 mm Midface reconstruction • 0.5 – 1.5 mm Maxillary orthognathic • 0.8 – 1.5 mm Mandibular orthognathic • 1.0 – 1.5 mm Genioplasty • 0.8 – 1.5 mm	N/A	Mandible reconstruction • 1.5 – 3.0 mm Midface reconstruction • 0.8 – 1.5 mm Orbital • 0.8 – 1.2 mm Maxillary orthognathic • 0.8 – 1.5 mm Mandibular orthognathic • 1.0 – 1.5 mm Genioplasty • 0.8 – 1.5 mm	The subject and secondary predicate device K170272 have equivalent ranges with differences in the lower bound of selected devices. The lower bound of the reconstruction/ trauma plate for the mandible and the midface are equivalent to reference devices K063790 and K050608, respectively. The mechanical equivalent is demonstrated by testing and analysis.
Profile Implants Thickness	Mandible reconstruction • 0.8 – 13 mm Midface reconstruction • 0.8 – 13 mm Orbital • 0.4 – 1.5 mm	Mandible reconstruction • 1.2 – 10 mm Midface reconstruction • 0.8 – 10 mm Orbital • 0.4 – 1.5 mm	N/A	The subject and secondary predicate device K173039 have equivalent ranges with difference in lower bound of the mandible reconstruction/trauma profile implant is equivalent to the mechanical strength of the plate in reference device K063790. Mechanical equivalence is demonstrated by testing and analysis.

VIII. INDICATIONS FOR USE COMPARISON

The subject device is a solution that includes software, patient-specific instruments (anatomical models, surgical guides, splints), and patient-specific implants.

The subject device is an update to its primary predicate device (K231520) to include patient-specific implants. The subject device and the primary predicate device share identical indication for use for the software and patient-specific instrumentation.

The subject device and the secondary predicate device (K173039) have an equivalent indication for use: bone fixation, reconstruction, and bone augmentation/enhancement in the mandible, midface, and chin.

The subject device and the secondary predicate device (K170272) have equivalent indication for use including target patient population. The subject device indication for use is equivalent to the combination of the primary predicate device and the secondary predicate devices.

IX. TECHNOLOGICAL COMPARISON (WITH PREDICATE DEVICES)

SIMILARITIES TO PREDICATE DEVICES

- The subject device is an update to the primary predicate device to add patient-specific implants to the indication. The tmCMF Solution has an equivalent indication for use as its primary predicate device K231520. The primary indication is to utilize pre-operative imaging data to perform surgical case planning and create patient-specific hardware. tmCMF implant indication for use is equivalent to that of the secondary predicate devices K173039 and K170272.
- The subject device software and primary predicate device software have equivalent technical characteristics. The subject device software is an update to the primary predicate device software to include new features. Those new features do not impact the features cleared under the primary predicate device.
- The subject device uses the same patient-specific tools and process flow as the primary predicate device K231520.
- The subject device has equivalent software to the primary predicate device K231520.
- The subject device has equivalent mechanical performance to the secondary predicate devices K173039 and K170272.
- The surgical guides, anatomical models, and dental splints are identical for the subject and primary predicate device.
- The newly introduced titanium alloy (Ti) surgical guides in the subject device share the same functional design as the polyamide (PA) surgical guides in the primary predicate device, with the only difference being the adaptation of the

thickness of the guide and assets to facilitate manufacturing using titanium alloy.

- The newly introduced Ti palatal insert in the subject device shares the same functional design as the acrylic palatal insert in the primary predicate device, with the only difference being the adaptation of the thickness of the palatal insert to facilitate manufacturing using titanium alloy.
- The implant shapes are identical between the subject and secondary predicate devices (K170272 and K173039).
- The subject and secondary predicate devices are anodized for device identification using color (K170272 and K173039).
- The subject device and predicate devices (K231520, K170272, and K173039) are sterilized using steam sterilization with a sterility assurance level of 1x10-6.
- The subject and secondary predicate devices (K170272 and K173039) are compatible with identical screws.
- Subject and secondary predicate devices (K170272 and K173039) offer titanium-based surgical guides to transfer pre-operative plan in surgery.

DIFFERENCES TO PREDICATE DEVICES

The subject device is an update to the primary predicate device K231520. Below is the summary of the differences.

- Software updates:
  - Support for plan review of the following procedures:
    - Augmentation
    - Orbital
    - Trauma
  - Patient-Specific Implant Review
  - Various enhancements
- Surgical Guides:
  - Expand surgical guides' offerings to include an option for manufacturing guides from titanium alloy (Ti-6Al-4V).
  - Update to Point of Care cleaning and sterilization instructions for non-sterile guides.
- Dental Splints:

- Expand dental splints offering to include an option for manufacturing palatal inserts from titanium alloy (Ti-6Al-4V).
- Update to Point of Care cleaning and sterilization instructions for non-sterile dental splints.

- Implants
  - Offering patient-specific implants that include both plates and 3D profile implants to support the following procedures: orthognathic, reconstruction, augmentation, and trauma for both mandible and midface (including orbital) anatomical.
  - The subject device for the mandible region is compatible with both locking screws in K063790 system, while the secondary predicate devices (K170272 and K173039) are compatible with the non-locking screws only.
  - The subject device is manufactured with titanium alloy, whereas the secondary predicate devices (K170272 and K173039) are manufactured with commercial grade pure titanium. Subject device offers sterile and non-sterile packaging for hardware devices (surgical guides, implants, anatomical models, and dental splints); whereas the predicate devices (K231520, K170272, and K173039) offer only non-sterile packaging.

X. 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 & Shelf-life

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.
Terminal sterilization, shelf life and shipping validations were performed according to ISO 11607-1, ISO 11607-2, ASTM D4169-22, and ASTM F1980-21.

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 and implants.

The biocompatibility evaluation was conducted on the subject device on the following endpoints per its contact classification.

- ISO 10993-5, “Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity”
- ISO 10993-10, “Biological evaluation of medical devices - Part 10: Tests for skin sensitization”
- ISO 10993-11, “Biological evaluation of medical devices - Part 11: Tests for systemic toxicity”
- ISO 10993-23, “Biological evaluation of medical devices - Part 10: Tests for irritation”
- ISO 10993-17, “Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents”
- ISO 10993-18, “Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process”
- USP <151> Pyrogen Test (USP Rabbit Test)

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.

Magnetic compatibility

Magnetic compatibility was conducted in accordance with ASTM F2182, ASTM F2052, and ASTM F2213.

Mechanical testing

Mechanical testing was performed to validate the mechanical integrity of the implant per ASTM F382-17.

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.

Performance verification	Testing demonstrated that the surgical guide and implants meets the predetermined acceptance criteria.
Locking screw compatibility verification	Testing demonstrated that the implant compatibility with locking screw design meets the predetermined acceptance criteria
Ti device manufacturing accuracy verification	Testing demonstrated that the manufacturing of titanium device meets the predetermined accuracy acceptance criteria.
Torque through resistance verification	Testing demonstrated that the implant resistance of screw torquing through meets predetermined acceptance criteria.
Hardware verification inspection and analysis	Testing demonstrated that instruments' implementation is compliant with the predetermined acceptance criteria.
Surgical case report verification	Testing demonstrated that the surgical case reports are compliant with predetermined acceptance criteria.
System validation	Testing demonstrated that the system has met user needs and is compliant with predetermined acceptance criteria.

XI. 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.