Materialise NV
Lina Ramirez
Regulatory Officer
Technologielaan 15
Leuven, 3001
BELGIUM

July 10, 2018

Re: K173039
Trade/Device Name: TruMatch CMF Titanium 3D Printed Implant
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: June 8, 2018
Received: June 11, 2018

Dear Lina Ramirez:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K173039

Device Name
TruMatch CMF Titanium 3D Printed Implant

Indications for Use *(Describe)*

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.

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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K173039- 510(k) SUMMARY

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92

Submitter information

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Date of preparation

This summary was last updated on July 9, 2018.

Submission information

Trade name(s)	**TruMatch CMF Titanium 3D Printed Implant** TruMatch CMF Ti 3D-Printed Plates and TruMatch CMF Ti 3D-Printed Surgical Guides TruMatch CMF Ti 3D-Printed Implants.
Common or Usual name	Bone plate
Classification name	Bone plate
Product code (classification regulation)	JEY
Classification Panel	Dental
Device class	Class II (21 CFR 872.4760)

Predicate device

The predicate device to which substantial equivalence is claimed to:

TruMatch CMF Titanium 3D Printed Implant System	
Bone plate and screw	
Trade or proprietary or model name	**TruMatch CMF Titanium 3D Printed Implant System**
510(k) number	K170272
Decision date	08/08/2017
Product code	JEY (21 CFR 872.4760)
Manufacturer	Materialise N.V.

Reference devices:

OsteoFab Patient Specific Facial Device - OPSFD	
Bone plate and screw	
Trade or proprietary or model name	**OsteoFab patient Specific facial Device**
510(k) number	K133809
Decision date	07/28/2014
Product code	KKY (21 CFR 878.3500)
Manufacturer	Oxford Performance Materials, Inc.

Synthes MatrixMANDIBLE Plate and Screw System	
Bone plate and screw	
Trade or proprietary or model name	**Synthes MatrixMANDIBLE Plate and Screw System**
510(k) number	K063790
Decision date	04/16/2007
Product code	JEY (21 CFR 872.4760)
Manufacturer	Synthes (USA)

Synthes Craniofacial Plate and Screw System	
Bone plate and screw	
Trade or proprietary or model name	**Synthes Craniofacial Plate and Screw System**
510(k) number	K080331
Decision date	04/30/2008
Product code	JEY (21 CFR 872.4760)
Manufacturer	Synthes (USA)

Synthes Matrixorthognathis Fixation System	
Bone plate and screw	
Trade or proprietary or model name	**Synthes Matrixorthognathis Fixation System**
510(k) number	K083388
Decision date	03/12/2009
Product code	JEY (21 CFR 872.4760)
Manufacturer	Synthes (USA)

The Synthes (USA) Neuro Plate and Screw System	
Bone plate and screw	
Trade or proprietary or model name	**The Synthes (USA) Neuro Plate and Screw System**
510(k) number	K042365
Decision date	11/18/2004
Product code	JEY
Manufacturer	Synthes (USA)

Synthes Patient Specific Cranial/Craniofacial Implant (PSCI)	
Plate, Cranioplasty, preformed, non-alterable	
Trade or proprietary or model name	**Synthes Patient Specific Cranial/Craniofacial Implant (PSCI)**
510(k) number	K053199
Decision date	12/14/2005
Product code	GXN (21 CRF) 882.5330
Manufacturer	Synthes (USA)

Device Information

Indications for use

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.

Device Description

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 implants feature a mesh-like structure. The mesh-like structures are designed with the same elementary pattern. This pattern was designed to obtain implants with mechanical properties close to those of bone and to allow for osseointegration.

The TruMatch CMF Titanium 3D Printed Implant can be used in combination with TruMatch CMF Titanium 3D Printed Accessories (patient-specific guides), cleared as SurgiCase guides (K103136) and TruMatch CMF Titanium 3D Printed Implant System (K170272). The guides are intended to aid with implant positioning.

The TruMatch CMF Titanium 3D Printed Implant provides surgeons with a patient-specific implant solution for plastic and reconstructive surgery. The device is constructed based on the patient's CT imaging data.

The TruMatch CMF Titanium 3D Printed Implant is designed to fit the patient's anatomy and is not contoured manually by the surgeon. The TruMatch CMF Titanium 3D Printed Implant is designed and manufactured with integrated screw holes to fixate the device to the bone using: MatrixMIDFACE (K050608), MatrixMANDIBLE (K063790, K121574), MatrixORTHOGNATHIC (K083388), MatrixNEURO screws (K123723, K042365), and Synthes Craniofacial Screw System (K050608).

The TruMatch CMF Titanium 3D Printed Implant contains the following applications:

Reconstruction applications: Orbital		
Brand name	TruMatch CMF Ti 3D-Printed Implants	
Material	Commercially pure titanium	
Type of design	Patient Specific	
Type of application	**Implant thickness**	**Patient specific associated instrument**
Orbital implants	0.4-1.5mm	Orbital guide

Reconstruction applications: Mandible, midface			
Brand name		TruMatch CMF Ti 3D-Printed Implant	
Material		Commercially pure titanium	
Type of design		Patient Specific	
Range of length		10-294mm	
Curvature		0°-12°/mm length	
Type of application	**Range of shapes**	**Implant thickness**	**Patient specific associated instrument**
Midface reconstruction	Mesh-shaped, contoured to the patient's anatomy • One/multi piece • One/multi layered	0.8-10mm	Midface guide
Mandibular reconstruction	Mesh-shaped, contoured to patient's anatomy • Single/double strut • Straight • Curved/crescent • Subcondylar • Plated extensions • One/multi layered • Combinations of the above	1.2-10mm	Mandibular guide

Comparison to the Predicate Device

Intended use:

	Subject device: TruMatch CMF 3D Printed Implants (K173039)	**Predicate device:** TruMatch CMF 3D Printed Implant System (K170272)
Product code	JEY	JEY
Classification	Class II	Class II
Intended Use	**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 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.

Both the subject device and the predicate device have the same indications for use: bone fixation and reconstruction in the maxillofacial skeleton, midface and chin. Both devices are used in the same anatomical regions. The subject device and the reference device (OsteoFab Patient Specific Facial Device – OPSFD), are both intended for bone augmentation/enhancement.

	Subject device: TruMatch CMF Titanium 3D Printed Implants (K173039)	**Predicate device:** TruMatch CMF Titanium 3D Printed Implant System (K170272)
Product code	JEY	JEY
Classification	Class II	Class II
Technical specification	Bone plate	Bone plate
Fixation method	Synthes screw system	Synthes screw system
Material(s)	Commercially pure titanium	Commercially pure titanium
Manufacturing method	Additive manufacturing	Additive manufacturing
Provided sterile?	No	No
Sterilization method	Moist heat	Moist heat
Device thickness	0.4 mm – 10 mm	0.8 mm – 3.0 mm
Patient-specific configuration?	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.

Both the subject and the predicate device are manufactured in commercially pure titanium. The subject device and the predicate device are fixed with screws.

Both the subject device and the predicate device are not provided sterile and have the same sterilization method, moist heat.

The subject device and the predicate device use an additive manufacturing technique to manufacture the implants. The subject device and the predicate are manufactured from commercially pure titanium in a mesh-like structure, and can be used with accessories (patient-specific guides).

The subject device and predicate device are made patient specific, manufactured from patient CT scan data.

The thickness range of the subject device falls into the thickness range of the predicate and the reference devices.

Performance data

The following non-clinical testing was conducted as a basis for the determination of substantial equivalence:

Test	Test method summary	Results
Mechanical testing	ASTM F382: Standard Specification and Test Method for Metallic Bone Plates	The results of this test indicate that the subject device has equivalent static bending properties and has non-inferior fatigue bending properties compared to the reference devices.
Sterilization testing	Steam sterilization validation according to ISO 17665-1 and ISO 14161, ISO11737-2:2009	The provided sterilization instructions effectively steam sterilize the subject device to a SAL of 10^{-6}.
Environmental conditioning and simulated shipping testing	According to ISTA 2A	The packaging specifications are found to be adequate to protect the device from damage during shipment.
Compatibility testing	Combination of user need validation lab and engineering rationale	The subject device is compatible with the Synthes fixation systems.

Biocompatibility test overview	
Test/assessment description	**Test report conclusion**
• Cytotoxicity: ISO 10993-5: Tests for in-vitro cytotoxicity - L929 Neutral red uptake Cytotoxicity	- no cytotoxic effect
• Sensitization: ISO 10993-10: Tests for irritation and delayed-type hypersensitivity – Kligman Maximization test	- in compliance with requirements of the ISO 10993-10 guidelines
• Intra-cutaneous reactivity: ISO 10993-10: Tests for irritation and delayed-type hypersensitivity – Intra-cutaneous Injection Test	- in compliance with requirements of the ISO 10993-10 guidelines
• Systemic toxicity: ISO 10993-11: Tests for systemic toxicity - Systemic injection test	- test passed and is considered negative based on standards set by ISO 10993-11
• Chemical characterization: ISO10993-18: Biological Evaluation of Medical Devices - Part 18: Chemical Characterization of Materials (2005)	- chemical characterization as per report
• Assessment of allowable limits for leachable substances: ISO 10993-17 (2009) "Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances"	- no toxicological concern remains - further biological testing are considered not justified

The following nonclinical tests were conducted on the TruMatch CMF Titanium 3D Printed Implant as a basis for the determination of substantial equivalence: Performance testing of the TruMatch CMF Titanium 3D Printed implants and accessories, including

- Mechanical performance of the subject device compared to the predicate and reference devices
- Compatibility testing
- Biocompatibility testing
- Sterilization testing
- Environmental conditioning and simulated shipping testing

Conclusion

Non-clinical tests demonstrate that the TruMatch CMF Titanium 3D Printed Implant is substantially equivalent to the predicate device.