DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Materialise N.V.
Lina Ramirez
Regulatory Officer
Technologielaan 15
Leuven, 3001 Belgium

August 8, 2017

Re: K170272
Trade/Device Name: TruMatch CMF Titanium 3D Printed Implant System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: July 14, 2017
Received: July 17, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S

for
Michael Ryan
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170272

Device Name

TruMatch CMF Titanium 3D Printed Implant System

Indications for Use *(Describe)*

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.

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

K170272

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 August 4, 2017.

Submission information

Trade name(s)	**TruMatch CMF Titanium 3D Printed Implant System** 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 devices

The primary predicate device to which substantial equivalence is claimed to:

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

Additional predicate devices to which substantial equivalence is claimed to:

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)

Device Information

Indications for use

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.

Device Description

The TruMatch CMF Titanium 3D Printed Implant System is intended for bone repositioning, fixation and reconstruction of the maxillofacial skeleton, midface, mandible and chin.
The TruMatch CMF Titanium 3D Printed Implant System provides a solution with patient-specific plates and patient-specific osteotomy and drill accessories, for the accurate transfer of the surgical plan to the operating room.
The TruMatch CMF Titanium 3D Printed Implant System contains the following applications:

		Orthognathic applications		
Brand name		TruMatch CMF Ti 3D-Printed Plates and TruMatch CMF Ti 3D-Printed Surgical Guides.		
Material		Commercially pure titanium		
Type of design		Patient Specific		
Range of length		20 mm maximum advancement		
Type of application	**Range of shapes**	**Plate thickness**	**Range ofcurvature/ angulation**	**Patient Specific associated instrument**
Maxillary fixation	Interconnected Straight, L-plate, Y-plate, double Y-plate, combinations of the above	0.8-1.5 mm	0-119°	Maxillary guide
Mandibular fixation BSSO	Single strut, double strut	1-1.5 mm	0-90°	BSSO guide
Mandibular fixation genioplasty	Interconnected Straight, curved, combinations of the above	0.8-1.5 mm	0-119°	Genioplasty guide

	Reconstruction applications: orbit		
Brand name	TruMatch CMF Ti 3D-Printed Implants.		
Material	Commercially pure titanium		
Type of design	Patient Specific		
Plate width	5.5-45 mm		
Type of application	**Plate thickness**	**Range of curvature**	**Patient Specific associated instrument**
Orbital fracture treatment	0.8-1.2 mm	12°/mm length	Orbital guide

		Reconstruction applications: Mandible, midface		
Brand name		TruMatch CMF Ti 3D-Printed Plates and TruMatch CMF Ti 3D-Printed Surgical Guides.		
Material		Commercially pure titanium		
Type of design		Patient Specific		
Range of length		20 mm maximum bridging of osteotomy gap Small: 20-120mm, Large: 20-294mm		
Type of application	**Range of shapes**	**Plate thickness**	**Range of curvature/angulation**	**Patient Specific associated instrument**
Mandibular reconstruction (small): Mandibular bone fixation	Straight, curved, crescent, lambda, trapezoidal, strut, subcondylar, combinations of the above	1.5-2 mm	12°/mm length	Mandibular guide
Mandibular reconstruction (large): Mandibular bone fixation and mandibular reconstruction with bone grafts	Single angle, double angle, curved, double barrel, combinations of the above	2-3 mm	12°/mm length	Mandibular guide
Midface reconstruction	Straight, Y, X, H, L, Double Y, Box, Strut, Oblique L, T	0.8-1.5 mm	12°/mm length	Midface guide

Comparison to Predicate Devices

	Subject device: TruMatch CMF 3D Printed Implant System	**Primary predicate device:** Synthes MatrixORTHOGNATHIC Plating System (K083388)	**Predicate device:** Synthes MatrixMANDIBLE Plate and Screw System (K063790)	**Predicate device:** Synthes Craniofacial Plate and Screw System (K080331)
Product code	JEY	JEY	JEY	JEY
Classification	Class II	Class II	Class II	Class II
Intended Use	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.	Synthes MatrixORTHOGNATHIC Plating System is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla, mandible, and chin in adolescents (greater than 12 to 21 years of age) and adults. Specific Indications for Use: • Fractures of the midface and craniofacial skeleton. • LeFort I osteotomies, sagittal split osteotomies, and genioplasties. • Orthognathic surgery including reconstructive procedures.	The MatrixMANDIBLE plate and screw system is intended for oral, maxillofacial surgery: • Trauma. • Reconstructive surgery. • Orthognathic surgery (surgical correction of dentofacial deformities)	The Synthes Craniofacial Plate and Screw System is intended for use in selective trauma of the midface and craniofacial skeleton, craniofacial surgery, reconstructive procedures and selective orthognathic surgery of the maxilla and chin

Both subject device and primary predicate have the same indications for use: orthognathic surgery, including Le Fort I osteotomies, saggital split osteotomies and genioplasty, reconstructive surgery and trauma of the mandible and maxillofacial skeleton.

The subject device is additionally indicated for mandible and chin reconstruction and for midface reconstruction including orbital reconstruction. These additional indications for use are covered by the secondary predicates.

Characteristics	TruMatch CMF Titanium 3D Printed Implant System	Synthes MatrixORTHOGNATHIC Plating System (K083388)	Synthes MatrixMANDIBLE Plate and Screw System (K063790)	Synthes Craniofacial Plate and Screw System (K080331)
Product code	JEY	JEY	JEY	JEY
Classification	Class II	Class II	Class II	Class II
Technical specification	Bone plate	Bone plate	Bone plate	Bone plate
Fixation method	Synthes screw system	Synthes screw system	Synthes screw system	Synthes screw system
Material(s)	Commercially pure titanium	Commercially pure titanium	Commercially pure titanium	Commercially pure titanium
Manufacturing method	Additive manufacturing	Machined	Machined	Machined
Provided sterile?	No	No	No	No
Sterilization method	Moist heat	Moist heat	Moist heat	Moist heat
Plate thickness	0.8 mm – 3.0 mm	0.5 mm – 1.0 mm	1.0 mm – 2.8 mm	0.2 mm – 0.5 mm
Patient-specific configuration?	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.	No. Devices are provided in a standard shape and matched to the patient's anatomy intra-operatively.	No. Devices are provided in a standard shape and matched to the patient's anatomy intra-operatively.	No. Devices are provided in a standard shape and matched to the patient's anatomy intra-operatively.

Both the subject device and all predicates are manufactured in commercially pure titanium and have the same fixation method.

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

The manufacturing technique differs between the subject device and the reference devices. While the subject device is manufactured by additive manufacturing, the predicate devices are machined.

The subject device is made patient specific, manufactured from patient CT scan data, while the predicate devices are provided in a standard shape and adapted to the patient intra-operatively.

Performance data

The following non-clinical testing was conducted 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 devices
  - Compatibility testing
- Biocompatibility testing
- Sterilization testing

An overview of the testing performed can be found below.

Performance testing overview		
Test	Test method summary	Results
Mechanical testing	ASTM F382: static and fatigue four point plate bending	The results of this test indicate that the subject device has a higher static bending strength and has non-inferior fatigue bending properties compared to the predicate devices.
Compatibility testing	Combination of user need validation lab and engineering rationale	The subject device is compatible with the Synthes fixation system.

Sterilization test overview	
Test / assessment description	**Test report conclusion**
Steam sterilization validation according to ISO 17665-1:2006, ISO 11737-2:2009 and ISO 14161:2009	- The results of the steam sterilization validation show that the implants, accessories and models can be sterilized to a SAL of 10-6 using the recommended steam sterilization instructions

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

Clinical performance of the device in the patient population of adolescents (greater than 21 to 21 years of age) and adults

To demonstrate clinical performance of the TruMatch CMF Titanium 3D Printed Implant System in the patient population of adolescents (greater than 21 to 21 years of age) and adults, 5 clinical studies including patients from 8-21 years and adults, were analyzed:

	Schendel et al. 1978[1]	Precious et al. 1985 (1)[2]	Precious et al. 1985(2)[3]	Li et al. 2017[4]	Heufelder et al. 2017[5] Subject device
Patient range of age	8-16 years	6-15 years	11-14 years	18-27 years	17-59 years
Treatment	Standard bone plate fixation	Standard bone plate fixation	Standard bone plate fixation	Patient-specific bone plate fixation	Patient-specific bone plate fixation
Results and analysis	The surgical-orthodontic correction of mandibular deficiency in growing children (8 to 16 years of age) can be employed to achieve excellent results. Mandibular advancement by a modified sagittal osteotomy proves to be an acceptable procedure with good skeletal stability. Dentofacial growth following surgery will be harmonious and not adversely affected. Direction of growth varies, with the mandibular plane angle becoming more vertical with an increasing mandibular plane angle.	Surgery for the correction of dentofacial deformities can be performed on children and adolescent patients with little morbidity and few complications.	The correction of dentofacial deformities in children using orthodontic and surgical means can be carried out reliably if careful attention is paid to the systematic evaluation of each deformity. Selected cases from more than 100 children whom we have treated are presented to illustrate salient clinical features of specific deformities.	The maximum positional and orientational differences between the planned and post-operative positions were within 1.1 mm and 3°. The system is capable of accurately and effectively transferring the surgical plan without the use of a surgical splint. No complications were reported in the article.	In this study all the operations were performed successfully, without any unexpected incidence. The results demonstrate the high predictability of maxillary positioning by CAD/CAM fabricated customized surgical guides and patient specific osteosynthesis plates.

Based on published literature findings of the subject device and similar bone plate devices and a risk analysis, it can be concluded that the subject device can be used for treatment of the adolescent patient population (greater than 12 to 21 years of age), if additional precautions are taken into account:

[1] Schendel S., Wolford M., Epker N. "Surgical advancement of the deficient mandible in growing children: Treatment results in twelve patients", Journal of Oral Surgery, Volume 45, No 3., pp 364-377.

[2] Precious D.S., McFadden L.R., Fitch S.J. "Orthognathic surgery for children, analysis of 88 consecutive cases" Int J. of Oral Surgery, 1985, Volume 14, pp 466-471

[3] Precious D.S., McFadden L.R., Fitch S.J. "Orthognathic surgery for children, analysis of 88 consecutive cases" Int J. of Oral Surgery, 1985, Volume 14, pp 466-471

[4] B. Li, S. Shen, W. Jiang, J. Li, T. Jiang, J.J. Xia, S.G. Shen, X. Wang. " A new approach to splint-less orthognathic surgery using a personalized orthognathic surgical guide system: A preliminary study, Int J. of Oral Surgery 2017

[5] Heufelder M., Wilde F., Pietzka S., Mascha F., Winter K., Schramm A., Rana M. "Clinical accuracy of waferless maxillary positioning using customized surgical guides and patient specific osteosynthesis in bimaxillary orthognathic surgery", Journal of craniomaxillofacial surgery, 2017

Important considerations in achieving quality outcomes for the treatment of facial deformities in growing patients include accurate diagnosis and patient selection and proper treatment planning.

Conclusion

Non clinical tests and a review of clinical performance data demonstrate that the TruMatch CMF Titanium 3D Printed Implant System is substantially equivalent to the predicate devices.