January 7, 2026

Materialise N.V.
% Polliane Carvalho
Regulatory Affairs Specialist
Technologielaan 15
Leuven, 3001
Belgium

Re: K253308
Trade/Device Name: "Materialise Personalized Guides and Models for Craniomaxillofacial Surgery" CMF Titanium Guides; CMF Plastic Models
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, And Their Accessories
Regulatory Class: Class II
Product Code: PPT, LLZ
Dated: December 10, 2025
Received: December 10, 2025

Dear Polliane Carvalho:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JULIA E. SLOCOMB -S Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.01.07 14:23:07 -05'00'

for Jaime Raven, Ph.D.
Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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.

510(k) Number *(if known)*
K253308

Device Name
"Materialise Personalized Guides and Models for Craniomaxillofacial Surgery" CMF Titanium Guides; CMF Plastic Models

Indications for Use *(Describe)*

CMF Titanium Guides

CMF Titanium Guides are intended to guide the marking of bone and/or guide surgical instruments in craniofacial surgery.

CMF Titanium Guides are used during bone repositioning/reconstruction surgical operations for orthognathic and reconstruction (including bone harvesting) indications.

CMF Titanium Guides are intended for children, adolescents and adults.

CMF Titanium Guides are intended for single use only.

CMF Titanium Guides are to be used by a physician trained in the performance of craniomaxillofacial surgery.

CMF Plastic Models

CMF Plastic Models are intended for visualization of the patient's anatomy, preparation of surgical interventions and fitting or adjustment of implants or other medical devices such as osteosynthesis plates or distractors, in craniofacial surgical procedures.

CMF Plastic Models are intended for infants, children, adolescents and adults.

CMF Plastic Models are intended for single use only.

CMF Plastic Models are to be used by a physician trained in the performance of craniomaxillofacial 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

The 510(k) summary is provided on the following page per 21 CFR 807.92(c).

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

Company name	Materialise NV
Establishment registration number	3003998208
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Zip code	3001
Country	Belgium
Phone number	+32 16 74 49 56
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Principal contact person	Polliane Carvalho
Contact title	Regulatory Affairs Specialist
Contact e-mail address	polliane.carvalho@materialise.com
Additional contact person	Jenny Jones
Contact title	Global Quality & Regulatory Manager, Medical
Contact e-mail address	jenny.jones@materialise.com

Submission date

Date of the Traditional 510(k) submission is September 29, 2025

Submission information

Trade name	Materialise Personalized Guides and Models for Craniomaxillofacial Surgery
Common or Usual name	CMF Titanium Guides CMF Plastic Models
Classification name	Cranial surgical planning and instrument guides
Product code (classification regulation)	Primary product code: PPT Secondary product code: LLZ
Classification Panel	Neurology
Device class	21 CFR 882.4310, Class II

Predicate device

The predicate device to which substantial equivalence is claimed to:

Materialise Personalized Guides and Models for Craniomaxillofacial Surgery	
Trade or proprietary or model name	**Materialise Personalized Guides and Models for Craniomaxillofacial Surgery**
510(k) number	K243637
Decision date	21/02/2025
Product code	DZJ, LLZ
Manufacturer	Materialise
Review Panel	Dental

Reference devices

SurgiCase Guide (cranial Application)	
Trade or proprietary or model name	**SurgiCase Guide**
510(k) number	K111558
Decision date	03/27/2012
Product code	HAW (21 CFR 882.4560)
Manufacturer	Materialise
Review Panel	Neurology

KLS Martin Individual Patient Solutions	
Trade or proprietary or model name	**KLS Martin Individual Patient Solutions (IPS) Planning System**
510(k) number	K201052
Decision date	08/31/2020
Product code	PPT (21 CFR 882.4310),
Manufacturer	KLS Martin
Review Panel	Neurology

Indications for use

Materialise Personalized Guides and Models for Craniomaxillofacial Surgery

Materialise Personalised Guides for Craniomaxillofacial Surgery

Materialise Personalised Guides for Craniomaxillofacial Surgery are intended to guide the marking of bone and/or guide surgical instruments in craniofacial surgery.

CMF Titanium Guides are used during bone repositioning/reconstruction surgical operations for orthognathic and reconstruction (including bone harvesting) indications.

CMF Titanium Guides are intended for children, adolescents and adults.

CMF Titanium Guides are intended for single use only.

CMF Titanium Guides are to be used by a physician trained in the performance of craniomaxillofacial surgery.

Materialise Personalized Models for Craniomaxillofacial Surgery
Materialise Personalized Models for Craniomaxillofacial Surgery are intended for visualization of the patient's anatomy, preparation of surgical interventions and fitting or adjustment of implants or other medical devices such as osteosynthesis plates or distractors, in craniofacial surgical procedures.
CMF Plastic Models are intended for infants, children, adolescents and adults.
CMF Plastic Models are intended for single use only.
CMF Plastic Models are to be used by a physician trained in the performance of craniomaxillofacial surgery.

Device Description

Materialise Personalized Guides and Models for Craniomaxillofacial Surgery combines the use of 3D pre-operative planning software with patient-matched guides and models to improve and simplify the performance of surgical interventions by transferring the pre-operative plan to surgery. Materialise Personalized Guides and Models for Craniomaxillofacial Surgery are used in the craniofacial skeleton or in craniomaxillofacial surgeries.

The surgical planning is based on medical images of the patient that are segmented in order to create a 3D representation of the patient's anatomy. The surgical treatment of the patient is simulated based on instructions provided by the surgeon and the patient-matched devices are tailored to the treatment and the patient's needs. The patient-matched devices are manufactured from commercially pure Titanium, polyamide, or clear acrylic by means of additive manufacturing technologies. The patient-matched devices are provided non-sterile.

Materialise Personalized Guides and Models for Craniomaxillofacial Surgery include CMF Titanium Guides and CMF Plastic Models.

The main parameters for the CMF Titanium Guides are summarized below.

Manufacturing	Additive manufacturing – Selective Laser Melting
Material	Commercially pure Titanium
Sterilization	Pre-vacuum steam sterilization at the hospital
Style	Mesh-shaped, contoured to patient's anatomy
Thickness	0.8 mm
Maximal guide length	94.2 mm for guides with solid-pattern links 104.2 mm for guides with mesh-pattern links 400 mm for bone graft harvesting guides 350 mm for guides used in cranial applications
Maximal guide width	400 mm for maxillofacial guides 200 mm for guides used in cranial applications
Pre-drilling barrels	Guidance of drill - Min height is 3.0 mm

	- Inner diameter equals drill diameter + 0.05mm Guidance of drill sleeve (DePuy Synthes ref 03.503.045) - Min height is 5.0 mm - Inner diameter is 3.57 mm
Fixation holes	Inner diameter - 2.2 or 2.7 mm for MatrixMANDIBLE screw - 2.1 mm for MatrixORTHOGNATHIC screw - 1.9 mm for MatrixMIDFACE screw Countersink diameter - 4.0 mm for MatrixMANDIBLE screw - 3.5 mm for MatrixORTHOGNATHIC & MatrixMIDFACE screw
Features	- Marking cylinders - Flanges - Cutting slot - Handle - Label

The main parameters for the CMF Plastic Models are summarized below.

Manufacturing	Additive manufacturing – Selective Laser Sintering (SLS) or Stereolithography (SLA)
Material	Polyamide or Clear acrylic
Sterilization	Pre-vacuum steam sterilization at the hospital
Style	Solid or hollow

Substantial Equivalence Comparison Indications for Use

Similarities to Predicate & Reference Devices

The subject device and the predicate (K243637) have the same indications for use except to add cranial use (craniofacial vs. facial).

The subject device and the reference devices (K201052, K111558) have similar indications for use in cranial surgeries.

Differences to Predicate & Reference Devices

The subject device expands the anatomical area compared to the predicate device (K243637) to include cranial from the reference devices (K201052, K111558) which are cleared for cranial surgeries.

Substantial Equivalence Comparison Technological Characteristics

Similarities to Predicate & Reference Devices

The subject device, the predicate device (K243637), and reference devices (K201052, K111558) share the same principles of operation where software is used to convert individual patient medical images to virtual models for surgical planning and design and fabrication of patient-specific devices for use in craniomaxillofacial surgery.

The subject device, the predicate device (K243637), and reference devices (K201052, K111558) use additive manufacturing methods to produce physical output devices. The subject device (CMF Titanium Guides), the predicate device (K243637) and a reference device (K201052) are produced with the additive manufacturing technology Selective Laser Melting (SLM). The subject device (CMF Titanium Guides) and the predicate device (K243637) are made of commercially pure Titanium as material. The subject device (CMF Plastic Models), the predicate device (K243637) and reference device (K201052) are produced with the additive manufacturing technology Stereolithography (SLA) using Acrylic Resin. The subject device (CMF Plastic Models) and the predicate device are produced with an additional additive manufacturing technology Selective Laser sintering with Polyamide.

The subject device is manufactured using identical methods to those cleared in the primary predicate (K243637).

The subject device, the predicate device (K243637), and reference devices (K201052, K111558) are provided non-sterile and require the end-user to process the devices using validated cleaning and sterilization methods prior to use as recommended in the device instructions for use.

Differences to Predicate & Reference Devices:

The subject device and the predicate device (K243637) have the same technological characteristics, there are no differences.

A device comparison table of the subject, predicate, and reference devices is provided below.

Characteristic	**Subject device** Materialise Personalized Guides and Models for Craniomaxillofacial Surgery	**Predicate device** Materialise Personalized Guides and Models for Craniomaxillofacial Surgery (K243637)	**Reference device** SurgiCase Guide (K111558)	**Reference device** KLS Martin Individual Patient Solutions (K201052)
Product code	PPT, LLZ	DZJ, LLZ	HAW	PPT
Classification	21 CFR 882.4310, Class II	21 CFR 872.4120, Class II	21 CFR 882.4560, Class II	21 CFR 882.4310, Class II
Indications for Use	Materialise Personalised Guides for Craniomaxillofacial Surgery are intended to guide the marking of bone and/or guide surgical instruments in craniofacial surgery. CMF Titanium Guides are used during bone repositioning/reconstruction surgical operations for orthognathic and reconstruction (including bone harvesting) indications. CMF Titanium Guides are intended for children, adolescents and adults. CMF Titanium Guides are intended for single use only. CMF Titanium Guides are to be used by a physician trained in the performance of craniomaxillofacial surgery. Materialise Personalized Models for Craniomaxillofacial Surgery are intended for visualization of the patient's anatomy, preparation of surgical interventions and fitting or adjustment of implants or other medical devices such as	Materialise Personalised Guides for Craniomaxillofacial Surgery are intended to guide the marking of bone and/or guide surgical instruments in facial surgery. CMF Titanium Guides are used during bone repositioning/reconstruction surgical operations for orthognathic and reconstruction (including bone harvesting) indications. CMF Titanium Guides are intended for children, adolescents and adults. CMF Titanium Guides are intended for single use only. CMF Titanium Guides are to be used by a physician trained in the performance of maxillofacial surgery. Materialise Personalized Models for Craniomaxillofacial Surgery are intended for visualization of the patient's anatomy, preparation of surgical interventions and fitting or adjustment of implants or other medical devices such as osteosynthesis plates or	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 during craniofacial osteotomies. The principal difference between the subject and predicate device is with respect to the anatomical region where the guides will be applied - craniofacial for the subject guides versus mandibular and maxillary for the predicate guides. SurgiCase Guides are intended for single use only.	The KLS Martin Individual Patient Solutions (IPS) Planning System is intended for use as a software system and image segmentation system for the transfer of imaging information from a computerized tomography (CT) medical scan. The input data file is processed by the IPS Planning 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, guides, and case reports for use in the marking and cutting of cranial bone in cranial surgery. The IPS Planning System is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options. Information provided by the software and device output is not intended to eliminate, replace, or substitute, in

	osteosynthesis plates or distractors, in craniofacial surgical procedures. CMF Plastic Models are intended for infants, children, adolescents and adults. CMF Plastic Models are intended for single use only. CMF Plastic Models are to be used by a physician trained in the performance of craniomaxillofacial surgery.	distractors, in mandibular and maxillofacial surgical procedures. CMF Plastic Models are intended for infants, children, adolescents and adults. CMF Plastic Models are intended for single use only. CMF Plastic Models are to be used by a physician trained in the performance of maxillofacial surgery.		whole or in part, the healthcare provider's judgment and analysis of the patient's condition.
Devices	CMF Titanium Guides and CMF Plastic Models	CMF Titanium Guides and CMF Plastic Models	CMF Guides	Anatomical models, cutting/marking guides, and case reports
Target Population	• Infant (CMF Models only) • Children • Adolescents • Adults	• Infant (CMF Models only) • Children • Adolescents • Adults	• Children • Adolescents • Adults	• Pediatric & Adult
Principles of Operation	Medical images used to plan surgery and design patient matched devices	Medical images used to plan surgery and design patient matched devices	Medical images used to plan surgery and design patient matched devices	Medical images used to plan surgery and design patient matched devices
Manufacturing	Additive manufacturing	Additive manufacturing	Additive manufacturing	• Epoxy/Resin, Acrylic: 3D (SLA) • CP Titanium: Traditional (Subtractive) • Ti-6Al-4V: 3D (Additive; SLM) • Polyamide: 3D (Additive; SLS)
Material(s)	• CMF Titanium Guides: Commercially Pure Titanium • CMF Plastic Models: Acrylic resin, Polyamide	• CMF Titanium Guides: Commercially Pure Titanium • CMF Plastic Models: Acrylic resin, Polyamide	Polyamide	• Anatomical Models: Epoxy/Resin, Acrylic • Cutting/Marking Guides: Polyamide, Ti-6Al-4V, CP Titanium
Sterilization	Non-sterile (Steam sterilization at hospital)	Non-sterile (Steam sterilization at hospital)	Non-sterile (Steam sterilization at hospital)	Non-sterile (Steam)

Substantial Equivalence Comparison Performance Data

The subject device and the predicate device (K243637) share the same non-clinical testing:

Device	Name	Test method	Conclusion
CMF Titanium Guides	Compatibility testing	Bench test with surgeons to verify compatibility of CMF Titanium Guides with Synthes Matrix screws and Materialise Standard+ Solutions screws and instrumentation	The CMF Titanium devices are compatible with the DePuy Synthes MatrixNEURO, MatrixMIDFACE, MatrixORTHOGNATHIC, MatrixMANDIBLE systems and Materialise Standard+ Solutions screws and instrumentation.
	Shape specification	The necessary geometrical accuracy of a CMF Titanium Guide for a surgeon to be comfortable with implanting a manually bent bone fixation plate	Bench tests with surgeons successfully demonstrated the necessary geometrical accuracy.
	Mechanical verification	The CMF Titanium Guides should be resistant to stresses applied during surgery. No guide specific mechanical testing is performed but this is covered by mechanical analysis of CMF Titanium Plates. Note: CMF Titanium Plates are leveraged devices for information purposes only and not subject to this submission.	Analysis and testing demonstrated the mechanical performance of the CMF Titanium Guides.
	Pediatric fit testing & useful life determination	The useful life of the CMF Titanium Guides was verified	The useful life of the CMF devices is found to be mainly exceeding 6 months

Device	Name	Test method	Conclusion
CMF Polyamide and Clear Acrylic Models	Resistance to handling forces during surgery	Use during validation activities	There are no expected handling forces exerted onto the models during use. Where models were available during the various Sawbones and cadaveric validation activities, none were reported to have deformed or broken during use.

Biocompatibility:

Device	Test method	Conclusion
CMF Titanium Guides	• Cytotoxicity: ISO 10993-5: Tests for in-vitro cytotoxicity - L929 Neutral red uptake Cytotoxicity	The result showed non-cytotoxicity.
	• Sensitization: ISO 10993-10: Tests for irritation and delayed-type hypersensitivity – Kligman Maximization test	The result showed non-sensitizer
	• Intra-cutaneous reactivity: ISO 10993-10: Tests for irritation and delayed-type hypersensitivity – Intra-cutaneous Injection Test	The result showed non-irritant.
	• Chemical characterization: ISO10993-18: Biological Evaluation of Medical Devices - Part 18: Chemical Characterization of Materials (2005)	The risk of toxicity is considered to be low.
	• 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.
	• Pyrogenicity ISO 10993-11: 2006	According to EP: The result showed no-pyrogenicity According to USP: The result showed non-pyrogenicity.

Device	Test method	Conclusion
CMF Plastic Models	Biocompatibility assessment per ISO 10993	The CMF Plastic Models are evaluated and safe for use with respect to biocompatibility.

The sterilization testing is similar for all devices.

Device	Test method	Conclusion
CMF Titanium Guides	Steam sterilization validation according to ISO 17665-1:2006,	The results of the steam sterilization validation show that the CMF Titanium Guides can be sterilized to a SAL of 10^{-6} using the recommended steam sterilization instructions
CMF Plastic Models	Steam sterilization validation according to ISO 17665-1:2006,	The results of the steam sterilization validation show that the CMF Plastic Models can be sterilized to a SAL of 10^{-6} using the recommended steam sterilization instructions

Substantial Equivalence Performance Conclusion

The subject device has similar indications for use, only differing in the anatomical region in which the device is intended, and identical technological characteristics as the predicate device. For cranial use, the subject device does not directly contact the cerebrospinal fluid (CSF) as it contacts the exterior portion of the skull (bone). The subject device is not intended for implantation similar to the predicate device.
Risk assessment has been conducted and does not raise new issues of safety and effectiveness, and demonstrates substantial equivalence to the predicate device.