



September 29, 2026

Pro3dure Medical GmbH
% Patricia Kontoudis
Regulatory Specialist
Kontoudis Consulting, LLC
804 Umbra St.
Baltimore, Maryland 21224

Re: K260031

Trade/Device Name: Thermeo® I MSI
Regulatory Class: Unclassified
Product Code: MQC
Dated: August 14, 2026
Received: August 14, 2026

Dear Patricia Kontoudis:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA

Assistant Director

DHT1B: Division of Dental and
ENT Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260031

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Please provide the device trade name(s).

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THERMEO® I MSI

Please provide your Indications for Use below.

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The THERMEO® I MSI blank is a disc intended for the fabrication of dental appliances such as mouthguards, nightguards, bruxism and TMJ splint appliances, and bite splints using CAD/CAM milling machines.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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3. 510(k) Summary - K260031

Device Trade Name:	THERMEO® I MSI
Manufacturer:	pro3dure Medical GmbH Am Burgberg 13 58642 Iserlohn Germany
Contact:	Mr. Frank Gischer Phone: +49 (0)2374 920050-14 Fax: +49 (0)2374 920050-50 Frank.gischer@pro3dure.com
Prepared by:	Ms. Patricia Kontoudis Regulatory Affairs Specialist Kontoudis Regulatory Consulting, LLC 804 Umbra Street Baltimore, MD 21224 Phone: (443)722-0126 Email: tricia@kontoudisconsulting.com
Date Prepared	January 5, 2026
Classification	Unclassified
Product Code	MQC
Predicate Device	Thermeo System (K212017)
Reference Device	GR Resin System MSI (K231775)
Indications for Use:	The THERMEO® I MSI blank is a disc intended for the fabrication of dental appliances such as mouthguards, nightguards, bruxism and TMJ splint appliances, and bite splints using CAD/CAM milling machines.
Device Description:	The THERMEO® I MSI blanks are pre-made by pro3dure using the two-part mixable device. The THERMEO® I MSI blank is intended to be used in conjunction with CAD/CAM milling technology systems.
Performance Testing:	Performance testing for the THERMEO® I MSI was performed in accordance with ISO 20795-2 including Flexural modulus, Flexural Strength, Tensile Strength, and Elongation at Break.
Biocompatibility:	Biocompatibility testing was conducted in accordance with ISO 10993-1.

Shelf-Life: The shelf life of the THERMEO® I MSI is 2 years. Testing was performed in accordance with ASTM F1980-16.

Conclusion: The THERMEO® I MSI is substantially equivalent in indications, technical characteristics, function, material, performance, biocompatibility, and shelf life to the predicate devices.

Comparison to Predicate Device:

Device	Subject Device: THERMEO® I MSI	Primary Predicate Device: Thermeo System (blank) (K212017)
Manufacturer	Pro3dure Medical GmbH	Pro3dure Medical GmbH
Indications for use	The THERMEO® I MSI blank is a disc intended for the fabrication of dental appliances such as mouthguards, nightguards, bruxism and TMJ splint appliances, and bite splints using CAD/CAM milling machines.	The Thermeo blank is a disc intended for the fabrication of dental appliances such as mouthguards, nightguards, bruxism and TMJ splint appliances, and bite splints using CAD/CAM milling machines.
Chemical Description	Methyl methacrylate-, BPA- and silicone-free material	Methyl methacrylate-, BPA- and silicone-free material
Manufacturing Technology	CAD/CAM milling technology systems.	CAD/CAM milling technology systems.
Product State	Blank	Blank
Performance Testing	ISO 20795-2	ISO 20795-2
Biocompatibility	ISO 10993	ISO 10993