April 8, 2022

Pro3dure Medical GmbH
Frank Gischer
Technical Director
Am Burgberg 13
Iserlohn, 58642 DEU
GERMANY

Re: K212017
Trade/Device Name: Thermeo System
Regulatory Class: Unclassified
Product Code: MQC
Dated: February 28, 2022
Received: March 10, 2022

Dear Frank Gischer:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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, M.ChE.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212017

Device Name
Thermeo System

Indications for Use *(Describe)*

Thermeo powder / Thermeo liquid is a heat cured, moldable, acrylic compound system for use in the fabrication of dental appliances such as mouthguards, nightguards, bruxism and TMJ splint appliances, and bite splints.

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.

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.

5. 510(k) Summary

510(k) Number:	K212017
Device Trade Name:	Thermeo System
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 Consultant, Regulatory Affairs 804 Umbra St.Baltimore, MD, 21224 Phone: (443)722-0126 pkontoudis@gmail.com
Date Prepared:	April 1, 2022
Classification:	Unclassified
Product Codes:	MQC
Primary Predicate Device:	Astron Dental Clearsplint ES (K111828)
Additional Predicate Device:	New Stetic S.A. Portux CAD/CAM Disc (K192153)
Reference Device:	Pro3dure GR-17 Resin System (K201827) Pro3dure GR Splint Resin System (K211415).
Indications for Use:	Thermeo powder / Thermeo liquid is a heat cured, moldable, acrylic compound system for use in the fabrication of dental appliances such as mouthguards, nightguards, bruxism and TMJ splint appliances, and bite splints. 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.
Device Description:	The Thermeo powder/Thermeo liquid is a two-compound mixable device, containing a powder component and a liquid component. The device is heat cured for the fabrication of dental appliances.

	The Thermeo blanks are pre-made by pro3dure using the two-part mixable device. The Thermeo blank is intended to be used in conjunction with CAD/CAM milling technology systems.
Performance Testing:	Performance testing for the Thermeo System 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 System is 2 years. Testing was performed in accordance with ASTM F1980-16.

Comparison to Predicate:

	Subject Device	Predicate Device	Additional Predicate Device
Device	**Thermeo System**	**Clearsplint ES (K111828)**	**Portux CAD/CAM Disc (K192153)**
Manufacturer	**Pro3dure Medical GmbH**	**ASTRON DENTAL CORPORATION**	**New Stetic S.A.**
Indications for use	Thermeo powder / Thermeo liquid is a heat cured, moldable, acrylic compound system for use in the fabrication of dental appliances such as mouthguards, nightguards, bruxism and TMJ splint appliances, and bite splints. 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.	Clearsplint ES is a heat cured, moldable, acrylic compound for use in the fabrication of dental appliances and dental prostheses devices including TMJ splint appliances, night guards, bruxism appliances and other devices as prescribed.	For the fabrication of crowns, bridges and structures for implant supported provisional removable denture and appliance prosthetics. - Provisional anterior and posterior crowns & bridges - Implant and abutment supported prosthetics. - Partial, complete and hybrid denture prosthetics (base and teeth) – Removable appliances (splint)
Comparison: The indications for the subject and the predicate devices include removable dental appliances.			
Chemical Description	Methyl methacrylate-, BPA- and silicone-free material	Methyl methacrylate-, BPA- and silicone-free material	Polymethylmethacrylate
Comparison: The subject and the predicate devices have similar chemical characterization.			
Manufacturing Technology	Thermeo powder / Thermeo liquid: Heat cured Thermeo blank: CAD/CAM milling technology systems.	Clearsplint ES: Heat cured	CAD/CAM milling technology systems.
Comparison: The subject and the predicate devices fabricate the final product by the same processes.			
Product State	Powder Liquid System Blank	Powder Liquid System	Blank
Comparison: The subject and the predicate devices are provided in the same physical states.			

Performance Testing	ISO 20795-2	ISO 20795-2	ISO 20795
Comparison: The subject and the predicate devices comply with the same performance standards.			
Biocompatibility	ISO 10993	ISO 10993	ISO 10993
Comparison: The subject and the predicate devices comply with the same biocompatibility standards.			

Conclusion: The Thermeo System is substantially equivalent in indications, technical characteristics, function, material. Performance, biocompatibility, and shelf life to the predicate device.