August 2, 2024

Bernhard Förster GmbH
Stefan Förster
CEO
Westliche Karl-Friedrich-Strasse 151
Pforzheim, 75172
GERMANY

Re: K241311
Trade/Device Name: Thermoforming Sheet Materials (Track A); Thermoforming Sheet Materials (Track B); Thermoforming Sheet Materials (Track E); Thermoforming Sheet Materials (Track Bleach)
Regulatory Class: Unclassified
Product Code: MQC
Dated: May 9, 2024
Received: May 9, 2024

Dear Stefan Förster:

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.

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

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)*
K241311

Device Name
Thermoforming Sheet Materials (Track A); Thermoforming Sheet Materials (Track B); Thermoforming Sheet Materials (Track E); Thermoforming Sheet Materials (Track Bleach)

Indications for Use *(Describe)*
Thermoforming Sheet Materials Track A, B, E and Bleach are indicated for the fabrication of orthodontic and dental appliances.

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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K241311 - 510(k) Summary

Prepared July 30, 2024

I) Applicant

Submitter	FORESTADENT Bernhard Förster GmbH
Address	Westliche Karl-Friedrich-Strasse 151 Pforzheim – Germany.
Contact	Mr. Stefan Förster
Telephone	+497231459116
E-mail	Stefan.Foerster@forestadent.com

II) Device

Trade Name	**Thermoforming Sheet Materials (Track A); Thermoforming Sheet Materials (Track B); Thermoforming Sheet Materials (Track E); Thermoforming Sheet Materials (Track Bleach)**
Common Name	Thermoforming Sheet Materials
Classification Name	Mouthguard, Prescription
Regulation Number	Unclassified
Product Code	MQC

III) Predicate Device

510(k) Number	K200125
Applicant	Erkodent Erich Kopp GmbH
Trade Name	Erkoloc-pro (blu / green / pink) Erkodur (freeze / -0M1 /-A1 / -A2 / -A3) Erkoflex (color / freestyle / -95 / -bleach) Erkolign Erkoplast PLA (-T/-W/-R) Erkolen Playsafe triple (-light)
Classification Name	Mouthguard, Prescription
Regulation Number	Unclassified
Product Code	MQC, KMY

IV) Indication For Use

Thermoforming Sheet Materials Track A, B, E and Bleach are indicated for the fabrication of orthodontic and dental appliances.

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V) Device Description

Thermoforming Sheet Materials are pre-shaped flat plastic discs. The sheets are plastified in appropriate thermoforming units and adapted onto patient individual plaster models. After cooling the sheets are removed from the model and trimmed to fit.
Thermoforming Sheet Materials include the following products:

Thermoforming Sheet Materials:
- Track A
- Track B
- Track E
- Track bleach.

VI) Comparison of Technological Characteristics

ITEM	PREDICATE DEVICE ERKODENT (K200125)	PROPOSED DEVICE FORESTANDENT TRACK	COMPARISON RESULT
FDA Product Code	MQC	MQC	same
FDA Device Classification Name	Mouthguard, Prescription	Mouthguard, Prescription	same
Indications for Use	Thermoforming Sheet Materials are indicated for the fabrication of orthodontic and dental appliances	Thermoforming Sheet Materials are indicated for the fabrication of orthodontic and dental appliances	same
Material	Resin / Thermoplastic	Resin / Thermoplastic	same
Fabrication	Thermo-Molding Custom-Fit	Thermo-Molding Custom-Fit	same
Prescription Device	Yes	Yes	same
Re-Usable Device	Yes, Single Consumer/Patient	Yes, Single Consumer/Patient	same
Sterility	Non-Sterile	Non-Sterile	same
Biocompatible	Yes	Yes	same

The above information demonstrates that, for the purposes of FDA regulation of medical devices, the TRACK A, TRACK BLEACH, TRACK E and TRACK B thermoforming sheet materials is substantially equivalent in terms of principles, indications and design to the legally marketed K200125 predicate: ERKODENT thermoforming sheet materials.

VII) Summary of Non-Clinical Testing

Non-clinical testing has been performed. All Thermoforming Sheet Materials are tested on their biocompatibility.

The tests have been performed according to the standard EN ISO 10993-1 and FDA Guidance Document titled “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."
The results of the testing demonstrated that the insolubility of the Thermoforming Sheet Materials is in compliance with EN ISO 10993-1 and the FDA Biocompatibility Guidance Document for the intended dental use.

Physical properties have been tested according to the applicable standards:

water absorption 24h/23 °C	ISO 62/1
density	ISO 1183
tensile strength	ISO 527
flectional strength	ISO 178
impact strength 23°C	ISO 179/1eU
Notch impact 24 °C	ISO 179/1eA
yield stress	ISO 527
elongation at break	ISO 527
E-modulus	ISO 527
hardness Shore	ISO 868
ball indentation hardness	ISO 2039/1
Vicat softening point	ISO 11357/3
temperature resistance	ISO 75/A
glass transition temperature	ISO 11357/3

VIII) Summary of Clinical Testing

No clinical testing was performed in support of this submission.

IX) Conclusion

The proposed device, Thermoforming Sheet Materials has the same performance specifications, fundamental scientific technology and intended use as that of the predicate device, Thermoforming Sheet Materials (K200125).

These devices are substantially equivalent, and there is no difference between the proposed subject device and the cited predicate device.