October 28, 2020

Erkodent Erich Kopp GmbH
℅ Jon Ward
President and CEO
AJW Technology Consultants, Inc.
11705 Boyette Road, Suite 503
Riverview, Florida 33569

Re: K200125
Trade/Device Name: Thermoforming Sheet Materials
Regulatory Class: Unclassified
Product Code: MQC, KMY
Dated: July 27, 2020
Received: July 30, 2020

Dear Jon Ward:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200125

Device Name
Thermoforming Sheet Materials

Indications for Use *(Describe)*

Thermoforming Sheet Materials 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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ERKODENT®

K200125

006 510(k) Summary

[As required by 21 CFR 807.92]

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter Information

Company Name:	Erkodent Erich Kopp GmbH
Company Address:	Siemensstrasse 3 72285 Pfalzgrafenweiler Germany
Company Phone:	+49 74 45 85 01-0
Company Fax:	+49 74 45 85 01-15
Contact Person:	Hans-Peter Kopp Heidrun Müller

Date Summary Prepared: 28 October 2020

B. Regulatory Correspondent

AJW Technology Consultants, Inc
11705 Boyette Road,Suite #503
Riverview, FL 33569, USA
Phone: 813-645-2855
Contact Person: Jon Ward
Email: wardjp@ajwtech.com

C. Device Identification

Generic name:	Thermoforming Sheet Materials
Specific trade names (Model names):	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
Product Code:	MQC
21 CFR Reference:	Unclassified
Subsequent product codes:	KMY, 21 CFR Reference: 872.5525
Panel:	Dental

D. Identification of Predicate Device

Predicate Devices:

Primary predicate:
Thermoform Sheet Materials and Accessories, K072522
Reference device:
Mouthguard and Aligner Materials K062828

E. Device Description:

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

F. Indications for use

Thermoforming sheet materials are indicated for the fabrication of orthodontic and dental appliances.

G. Technological characteristics

All of the components found in Thermoforming Sheet Materials have been used in legally marketed devices and/or were found safe for dental use. The Thermoforming Sheet Materials have been tested on their biocompatibility.

The proposed device, Thermoforming Sheet Materials has the same performance specifications, fundamental scientific technology and intended use as that of the predicate devices and is therefore substantially equivalent.

H. Comparison table: Predicate Devices and Proposed Device

Attributes	Predicate Device (Primary) Thermoform Sheet Materials and Accessories Dentsply International, Inc. (K072522)	Predicate Device (Reference) Mouthguard and Aligner Materials Dentsply International, Inc. (K062828)	Proposed Device Thermoforming Sheet Materials ERKODENT
FDA Product Code	MQC, NXC	MQC, NXC, KMY	MQC, KMY

Attributes	Predicate Device (Primary) Thermoform Sheet Materials and Accessories Dentsply International, Inc. (K072522)	Predicate Device (Reference) Mouthguard and Aligner Materials Dentsply International, Inc. (K062828)	Proposed Device Thermoforming Sheet Materials ERKODENT
FDA Device Classification Name	Mouthguard, Prescription	Mouthguard, Prescription	Mouthguard, Prescription
Indications for Use	THERMOFORM SHEET MATERIALS AND ACCESSORIES are indicated for the fabrication of orthodontic and dental appliances.	MOUTHGUARD AND ALIGNER MATERIALS are indicated for the fabrication of orthodontic and dental appliances such as aligners, bite planes, mouthguards, nightguards, snoring appliances, splints, retainers, repositioners, and temporary bridges.	THERMOFORMING SHEET MATERIALS are indicated for the fabrication of orthodontic and dental appliances
Material	Resin/Thermoplastic	Resin/Thermoplastic	Resin/Thermoplastic
Fabrication	Thermo-Molding Custom-Fit	Thermo-Molding Custom-Fit	Thermo-Molding Custom-Fit
Prescription Device	Yes	Yes	Yes
Re-Usable Device	Yes, Single Consumer/Patient	Yes, Single Consumer/Patient	Yes, Single Consumer / Patient
Sterility	Non-Sterile	Non-Sterile	Non-Sterile
Biocompatible	Yes	Yes	Yes

I. Non-Clinical Testing

Non-clinical testing have 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 No. FDA-2013-D-0350. Biological effects to be considered for leachables are cytotoxicity, mucosa irritation, sensitization, acute systemic and subchronic toxicity, genotoxicity.

The results of the testing prove that the insolubility of the Thermoforming Sheet Materials is in compliance with EN ISO 10993-1 and FDA Guidance Document No. FDA-2013-D-0350 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

J. Conclusion of the testing

The proposed device, Thermoforming Sheet Materials has the same performance specifications, fundamental scientific technology and intended use as that of the predicate devices, Thermoform Sheet Materials and Accessories (K072522) and Mouthguard and Aligner Materials (K062828).

These devices are substantially equivalent, and any differences between the proposed device *Thermoform Sheet Materials and Accessories* and the cited predicate devices do not introduce any new issues.