November 7, 2019

Dreve Dentamid GmbH
% Nevine Erian
Regulatory Consultant
BQC Consulting LLC
24341 Barbados Dr.
Dana Point, California 92629

Re: K190571
Trade/Device Name: StoneBite and StoneBite scan
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: July 10, 2019
Received: October 9, 2019

Dear Nevine Erian:

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 Nandkumar, Ph.D.
Acting 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)*

K190571

Device Name

StoneBite© and StoneBite© scan

Indications for Use *(Describe)*

StoneBite© and StoneBite© scan are addition-curing silicones for bite registrations.

StoneBite© is indicated for:

- bite registrations
- key for intraoral registration

StoneBite© scan is indicated for:

- bite registrations
- key for intraoral registration
- optical collection of data in CAD/CAM/CIM systems

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K190571

510(k) Summary

Submitter **Dreve Dentamid GmbH**
Max-Planck-Strasse 31
59423 Unna, Nordrhein-Westfalen, Germany
Establishment Reg. No. 1000486347

Contact Dr. Reiner Altmann
Head of Quality Management & Regulatory Affairs
Phone +49 2303 8807 14
Fax +49 2303 8807 581
E-Mail reiner.altmann@dreve.de

Official Correspondent Nevine Erian
Regulatory Consultant
BQC Consulting LLC
24341 Barbados Dr.
Dana Point, CA 92629
Phone (949) 370-7155
Fax (949) 240-8829
E-mail nevine@bqcconsulting.com

Date Prepared November 5, 2019

- **Trade/Device Name** StoneBite© and StoneBite© scan
- **Common Name** Impression Materials
- **Classification Name** Impression Material
- **Regulation Number** 21 CFR 872.3660
- **Product Code** ELW

Predicate Devices

Futar® (Kettenbach GmbH & Co. KG) – K081120 – ***Primary Predicate***

Reference Devices

Dynax© (Dreve Dentamid GmbH) – K171562

Counter-Fit© (Clinician's Choice Dental Products, Inc) - K081017

Aquasil© (Dentsply Intl.) – K021410

Exacta Fresh© (Exacta Dental Products, Inc.) – K053427

Device Description

StoneBite and StoneBite scan are addition-curing silicones for bite registration, used in dental applications to produce an accurate reproduction of the patient's occlusal record.

Statement of Intended Use

StoneBite and StoneBite scan are vinylpolysiloxane based materials for biteregistration.

Statement of Indication for Use

StoneBite© and StoneBite© scan are addition-curing silicones for bite registrations.

StoneBite© is indicated for:

- bite registrations
- key for intraoral registration

StoneBite© scan is indicated for:

- bite registrations
- key for intraoral registration
- optical collection of data in CAD/CAM/CIM systems

Material Composition

StoneBite and StoneBite scan are vinyl polysiloxane based materials.

Technological Characteristics

StoneBite and StoneBite scan are medium-body elastomeric bite registration materials for dental applications to produce an accurate reproduction of the patient's occlusal record. StoneBite and StoneBite scan are two-component (base and catalyst) addition-curing materials.

Non-Clinical Performance Testing

StoneBite and StoneBite scan were tested and met the applicable requirements of the FDA Recognized Consensus standard:

- ISO 4823:2015 – Dentistry, Elastomeric Impression Material

Bench test results allowed us to conclude that StoneBite and StoneBite scan meet their intended use.

Biocompatibility

StoneBite and StoneBite scan meet biocompatibility requirements of the following standards:

- ISO 10993-1:2009 – B*iological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*
- ISO 7405:2008 Dentistry – *Evaluation of Biocompatibility of Medical Devices Used in Dentistry*

Dynax© (K171562), Aquasil© (K021410), Counter-Fit© (K081017), and Exacta Fresh© (K053427) are Reference Devices in conjunction with biological testing and literature review to support the biocompatibility of StoneBite and StoneBite scan.

Clinical Performance Data

Not applicable. No human clinical testing was performed to support the substantial equivalence of StoneBite and StoneBite scan.

Substantial Equivalence

The technical characteristics of StoneBite materials are substantially equivalent to the K081120 Primary Predicate device. The Reference Devices, Dynax© (K171562), Aquasil© (K021410), Counter-Fit© (K081017), and Exacta Fresh© (K053427), are only referenced to support the biocompatibility of the subject devices.

Material

StoneBite and StoneBite scan are similar in chemical composition as the predicate devices.

Physical Properties

StoneBite and StoneBite scan have similar physical properties as the predicate devices.

Technical Comparison of StoneBite and StoneBite scan to Predicate Devices

Attribute	StoneBite and StoneBite scan	Futar
Indications		
Bite registration	StoneBite – Yes StoneBite scan – Yes	Futar D – Yes Futar Cut & Trim Fast – Yes
Key for intraoral registration	StoneBite – Yes StoneBite scan – Yes	Futar D – Yes Futar Cut & Trim Fast – Yes
Optical collection of data in CAD/CAM/CIM systems	StoneBite – No StoneBite scan – Yes	Futar D – No Futar Cut & Trim Fast – Yes
Physical Property		
Type 2 - Medium-body per ISO 4823	StoneBite – Yes StoneBite scan – Yes	Futar D – Yes Futar Cut & Trim Fast – Yes
Working Time	StoneBite – 30 sec StoneBite scan – 30 sec	Futar D – ≤ 30 sec Futar Cut & Trim Fast – ≤ 15 sec
Intraoral Setting Time	StoneBite – ≥ 50 sec StoneBite scan – ≥ 50 sec	Futar D – ≥ 90 sec Futar Cut & Trim Fast – ≥ 45 sec
Linear Dimensional Change	StoneBite – < 0.2% StoneBite scan – < 0.2%	Futar D – 0.1% Futar Cut & Trim Fast – 0.2%
Final Hardness	StoneBite – 48 ± 2 Shore D StoneBite scan – 32 ± 2 Shore D	Futar D – Approx. 43 Shore D Futar Cut & Trim Fast – Approx. 35 Shore D
Material Type	Vinylpolysiloxane based	Vinylpolysiloxane based
Technical Attributes		
Physical Configuration	S-50 Double cartridge system 1:1	S-50 Double cartridge system 1:1
Mixing Element	Mixing Tip	Mixing Tip
Scannable	StoneBite – No For StoneBite scan – Yes	Futar D – No Futar Cut & Trim Fast – Yes
Mode of Action	Addition-curing bite registration	Addition-curing bite registration

Conclusion

Information provided in this application demonstrates that StoneBite & StoneBite scan are equivalent to the predicate devices. StoneBite & StoneBite scan have same indications for use, similar material composition, similar physical properties and technological characteristics as Futar products.