Dreve Dentamid GmbH
Rilchard Keen
Consultant
1151 Hope Street
Stamford, Connecticut 06907-1659

April 13, 2018

Re: K171562
Trade/Device Name: Dynax clear, Dynax putty, Dynax heavy body, Dynax light, Dynax mono
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: February 22, 2018
Received: March 14, 2018

Dear Richard Keen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Dreve Dentamid

510(k) Number (if known): K171562

Device Name: Dynax Dental Impression Material:

- Dynax clear
- Dynax putty
- Dynax heavy body
- Dynax light
- Dynax mono

Indications for Use:

Dynax Dental Impression Material is intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums.

Prescription Use (21 CFR Part 801 Subpart D)	☒	and/or	Over-The-Counter Use (21 CFR Part 801 Subpart C)	☐

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Dreve Dentamid GmbH
Max-Planck-Straße 31
59423 Unna/Germany
Tel.: +49 2303 8807-0
Fax: +49 2303 8807-55
E-Mail: dentamid@dreve.de

Internet: www.dreve.com/dentamid
Lieferadresse: Einsteinstr. 36
Geschäftsführer:
Dr. Volker Dreve, Dino Marchetti
Sitz: 59423 Unna
Reg.-Gericht: Hamm HRB 3712

Sparkasse Unna
Kto.-Nr. 43 000
BLZ 443 500 60
BIC: WELADED1UNN
IBAN: DE 26 44350060 0000043000

Commerzbank AG Dortmund
Kto.-Nr. 03 222 354 00
BLZ 440 800 50
BIC: DRESDEFF440
IBAN: DE 35 44080050 0322235400

Postbank Dortmund
Kto.-Nr. 6 493 469
BLZ 440 100 46
BIC: PBNKDEFF
IBAN: DE 42 44010046 0006493469

Dreve Dentamid

510(k) Summary

Sponsor:	Dreve Dentamid GmbH Dr. Reiner Altmann (Head of Quality Management & Regulatory Affairs) Max-Planck-Str. 31 59423 Unna/Germany Phone: +49 2303 8807 14 Email: reiner.altmann@dreve.de
Consultant:	Mr. Richard Keen Compliance Consultants 1151 Hope Street Stamford, CT 06907-1659 Phone: 203 329 2700 F 203 329 2345 Email: rkeen@fda-complianceconsultants.com
Date:	April 12th, 2018
510(k) number:	K171562
Proprietary Name:	Dynax® clear, models D6121 & D6122 Dynax® putty, model D6101 Dynax® heavy body, models D6112 & 6113 Dynax® light, models D6103 & 6104 Dynax® mono, models D6106 & 6107
Common Name:	Dental Impression Material
Device Classification Name:	Impression material
Classification Number:	21 CFR 872.3660
Product Code:	ELW
Reviewing Group:	Dental
Device Classification:	Class 2 per 21 CFR 872.3660
Establishment registration No.	1000486347
Predicate Device:	K053427 Fresh Bold, Impression material

Trademark Notice: All Trademarks used other than those of Dreve Dentamid GmbH are registered to their respective owners.

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Device Description

Dynax® Dental Impression Materials are designed for dental applications to define and reproduce the structure of a patient's teeth and gums for producing crowns, bridges, occlusal and dental implant. Base and catalyst components are mixed in equal ratio 1:1, placed into an impression tray and inserted into the patient's mouth. The material will conform to the patient's dentition and when set will produce a reproduction of the patient's teeth and occlusion.

Intended Use

Dental Impression Material on the basis of vinylpolysiloxane

Indications for Use:

Dynax® Dental Impression Material is intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums.

Technological Characteristics

Design

The Dynax® Dental Impression Materials are similar in design to the predicate listed above. Same as the predicate the Dynax® Dental Impression Materials are intended to reproduce the structure of a patient's teeth and gums to make crowns, bridges, occlusal and dental implant impressions. They use similar technological characteristics and principles. Both materials are two component silicones being mixed in 1:1 ratio to start the vulcanizing process.

Material

As the predicate material the Dynax® Dental Impression Materials are based on mixtures of vinyl terminated polydimethylsiloxanes and filler materials with platinum catalyst and methylhydrosiloxane dimethylsiloxane copolymers. An assessment of the biocompatibility according to FDA Recognized Consensus Standard ISO 10993-1 is included in this application. As a result of this assessment/testing we conclude that the device is safe for its intended use and does not show any unacceptable risks for users, patients and third parties.

This is a *prescription only* material. The labeling and working instructions are designed for health care professionals.

Testing

The Dynax® Dental Impression Materials have been designed, developed, tested and produced according to ISO 13485; CAN/CSA ISO 13485 and European Medical Device Directive 93/42/EEC. The quality system is certified by a Notified Body.

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Testing has confirmed that these devices meet their product specification. A series of in-house tests have been conducted to verify the intended signals are accurate and can maintain performance over its useful life.

Substantial Equivalence

Information provided in this application shows that the product is substantially equivalent to the predicate device in intended use, performance, materials and application. The differences between these devices are incidental and not significant and do not raise new questions of safety or effectiveness.

Safety and Effectiveness

There are no substantial differences between the Dynax® (clear, putty, heavy body, light, mono) and the predicate device: the K053427 Fresh Bold, Impression material. In fact, the Dynax® (clear, putty, heavy body, light, mono) and the predicate device: the K053427 Fresh Bold, Impression material are virtually identical with minor exceptions.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. The Dynax® (clear, putty, heavy body, light, mono) has benefited from design, development, testing and production procedures that conform to our in-house quality systems.

Harmonized Test

This device is the same (within the definition of design controls) as the device cleared in K053427 - with the addition of qualifying this device to the indicated harmonized standards. This device may be used interchangeably with the predicate.

Summary of the Technological Characteristics of this Device compared to the Predicate:

Comparable Parameter	Dynax® (clear, putty, heavy body, light, mono)	K053427 Fresh Bold, Impression material
Intended Use	Dental Impression Material on the basis of vinylpolysiloxane	The intended use of this material is for a trained dental to reproduce the structure of patient's teeth and gums to make crowns, bridges, occlusal and dental implant impressions.

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Indications for Use	Dynax® Dental Impression Material is intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums.	Fresh, Dental Impression material is intended for use with all crowns, bridges, occlusal and dental implant impression techniques to reproduce the structure of a patient's teeth and gums.
Working / Processing time	90 sec	90 - 120 sec
Setting time / Time in the mouth	90 sec	120 - 140 sec
Hardness	46 - 70 Shore A	42 - 70 Shore A
Working humidity	50 %	50 %
Dimensional accuracy	99.9 % - 99.2 %	99.9 % - 99.2 %
Stability (linear dimensional change)	< 0.2 % typical	< 0.1 % typical
Consistency	Type 0 - type 3 DIN EN ISO 4823	Type 0 - type 3 DIN EN ISO 4823
Design	Dynax® putty is sold in tubs of 2 x 35 ml and 2 x 450 ml. Dynax® light, mono, heavy body and clear are sold in 50 ml double cartridges.	Fresh Bold liquid putty impression system is sold in tubs of 2 x 450 ml. Fresh Bold light body, monophase, heavy body and clear bite are sold in packs of 2 x 50 ml double cartridges plus mixing canulas
Material	Dynax® putty, light, mono and heavy body: Mixture of vinyl terminated polydimethylsiloxanes and filler materials with platinum catalyst and methylhydrosiloxane dimethylsiloxane copolymers. Dynax® clear: Mixture of vinyl terminated polydi-methylsiloxanes and silicic acid with platinum catalyst and methyl-hydrosiloxane dimethylsiloxane copolymers.	Fresh Bold liquid putty, light body, monophase and heavy body: Mixture of vinyl terminated polydimethylsiloxanes and filler materials with platinum catalyst and methylhydrosiloxane dimethylsiloxane copolymers. Fresh Bold clear bite: Mixture of vinyl terminated polydi-methylsiloxanes and silicic acid with platinum catalyst and methyl-hydrosiloxane dimethylsiloxane copolymers.
Chemical Description	Room temperature vulcanizing 2-components silicone	Room temperature vulcanizing 2-components silicone

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Method of manipulation	Perforated impression trays	Perforated impression trays
Consensus standards	EN ISO 13485: 2012 + AC:2012 ISO 7405: 2nd Edition ISO 4823: 4th Edition ISO 14971: 2nd Edition ISO 10993-1: 2009	EN ISO 13485: 2012 + AC:2012 ISO 7405: 2nd Edition ISO 4823: 4th Edition ISO 14971: 2nd Edition ISO 10993-1: 2009

Conclusion

The technological characteristics of the subject device and the predicate are virtually identical and both devices have the same intended use. Any noted differences between. Dynax® Dental Impression Material and the predicate do not raise new questions of safety or effectiveness.

Dynax® Dental Impression Material is substantially equivalent to the predicate Fresh Bold, Impression material based on design, material, performance, chemical description and consensus standards.

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