



Food and Drug Administration
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Dreve Dentamid Gmbh
Reiner Altmann
Head Of Quality Management & Regulatory Affairs
Max-Planck-Strasse 31
Unna, Norderhein-Westfalen, 59423 DE

April 5, 2018

Re: K162408

Trade/Device Name: Nano Varnish, Plaquit, Lightpaint On Surface
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material For Resin Fillings
Regulatory Class: Class II
Product Code: EBD
Dated: February 28, 2018
Received: March 5, 2018

Dear Reiner Altmann:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mary S. Runner -S

for 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

510(k) Number (if known)
K162408

Device Name
NanoVarnish
Plaque
Lightpaint on Surface

Indications for Use (Describe)

Varnish for final coating for resin temporaries to produce a smooth and shiny surface.

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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510(k) Summary

Submitter: Dreve Dentamid GmbH
Max-Planck-Straße 31
59423 Unna / Germany

Establishment Reg. No. 1000486347

Contact: Dr. Reiner Altmann
(Head of Quality Management &
Regulatory Affairs)
Phone: +49-2303-8807-0
E-mail: reiner.altmann@dreve.de

Official Correspondent: Mr. Michael Breer
(Quality Management Representative)

Date: April 4th, 2018

510(k) number: K162408

- **Common Name:** Dental sealing lacquer
- **Trade/Device Name:** NanoVarnish, Plaquit and Lightpaint on Surface
- **Classification Name:** Coating material for resin fillings
- **Device Classification:** Class II per 21 CFR 872.3310
- **Product Code:** EBO

Primary Predicate Device: K123761 VITA ENAMIC® Glaze

Device Description

The light-curing one-component dental sealing lacquers NanoVarnish, Plaquit and Lightpaint on Surface are designed for coating resin parts of complete and partial dental prosthesis and for provisional crowns and bridges. The lacquer is applied to a dental restoration and cured with the help of a dental light-curing unit.

Intended Use:

Dental sealing lacquer for coating resin temporaries



Kopierschutz: s.Mitglied des Bundesverbandes der Zahnärztekammern in Deutschland e.V.

VDDI
Dental Solutions
German Manufacturers

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

Marchetti Sitz: 59423 Unna
Reg.-Gericht: Hamm HRB 3712

Internet:
www.dreve.com/dentamid
Lieferadresse: Einsteinstr. 36
Geschäftsführer:
Dr. Volker Dreve, Dino



Sparkasse
Unna Kto.-
Nr. 43 000
BLZ 443 500 60
BIC:WELADED1
UNN 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

Indications for Use:

Varnish for final coating for resin temporaries to produce a smooth and shiny surface.

Technological Characteristics

Design

The predicate also includes powder and liquid material for characterization of the surface of dental restorations which is not part of the Dreve dental sealing lacquers. However, the kit also includes VITA ENAMIC® Glaze which is designed to seal and create a smooth and glossy surface same as the Dreve dental sealing lacquers.

The Dreve dental sealing lacquers are the same in respect of design compared to the predicate. Same as the predicate the Dreve light-curing dental sealing lacquers are intended to be applied in-vitro for the purpose of coating dental restorations. They use the same technological characteristics and principles. They are one-component light-curing resins and polymerize by using dental light-curing units.

Material

Same as the predicate the Dreve dental sealing lacquers are based on multifunctional acrylates with photo initiators. The lacquers polymerize in a UV-light initiated free radical addition reaction.

The dental sealing lacquers and the VITA ENAMIC® Glaze are *prescription only* material. The labeling and working instructions are designed for health care professionals.

Testing

The Dreve dental sealing lacquers 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.

Testing has confirmed 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. The new device has been also tested in comparison with the predicate and the main characteristics are the same.



Substantial Equivalence

Information provided in this application shows that the new device is substantially equivalent to the predicate device in intended use, performance, materials, technological characteristics and application. The differences between these devices are incidental and not significant.

Biocompatibility

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 raise any new questions compared with the predicate.

Furthermore there are no substantial differences between the Dreve dental sealing lacquers and the predicate device K123761 Vita Enamic® Glaze. In fact, the Dreve dental sealing lacquers and the predicate device are virtually identical. They are the same in function and similar in composition with only minor exceptions.



Harmonized Test

This device is the same (within the definition of design controls) as the device cleared in K123761 - 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 the new device compared to the predicate:

Comparable Parameter	Dental sealing lacquers (NanoVarnish, Plaquit, Lightpaint on Surface)	VITA ENAMIC® Glaze K123761
Intended Use	Dental sealing lacquer for coating resin temporaries	Sealing lacquer for the surface characterization of dental restorations.
Indications for Use	Varnish for final coating for resin temporaries to produce a smooth and shiny surface.	VITA ENAMIC® Stains are indicated for shade customization and characterization of the surface of dental restorations made of hybrid ceramic resin and resin materials. <i>The Glaze material provided in the Stains sets the final coating providing protection of the stains from abrasion wear.</i>



Design	Supplied in glass bottles. 	Supplied in glass bottles. 
Chemical description	One component UV-light curing (meth)acrylic lacquer radical polymerization	One component UV-light curing (meth)acrylic lacquer radical polymerization
Appearance visual	Colorless, liquid	Colorless, liquid
Viscosity at 23°C	s; 0.15 - 0.02	s; 0.15
Pencil hardness (acc. to Wolff Wilborn)	2 H	2 H
Working / Processin time	< 1 min.	< 1 min.
Curing time	<u>approx. 3 - 5 min.</u>	<u>approx. 3 min.</u>
Temperature	<u>Room temperature</u>	<u>Room temperature</u>
Shelf life	<u>2 years</u>	<u>2 years</u>
Conformance to consensus standard	EN ISO 13485: 2012 + AC:2012 ISO 7405: 2008 ISO 14971: 2007 ISO 10993-1: 2009	EN ISO 13485: 2012 + AC:2012 ISO 7405: 2008 ISO 14971: 2007 ISO 10993-1: 2009

The difference of the Intended Use and the Indications for Use of the Dreve dental sealing lacquers (Plaquit, NanoVarnish and Lightpaint on Surface) and the predicate are due to the availability of the predicate K123761 VITA ENAMIC® Glaze in a set of devices. All components of this set are used for shade customization and characterization of the surface of dental restorations but the VITA ENAMIC® Glaze is for coating purpose only as described in the IFU (*The Glaze material provided in the Stains set is the final coating providing protection of the stains from abrasion wear.*).

Conclusion

The technological characteristics of the subject device and the predicate are virtually identical and both devices have generically the same intended use.



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Dental Solutions
German Manufacturers



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
Geschäftsfohrer:

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 440 000 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 dental sealing lacquers are substantially equivalent to the predicate VITA ENAMIC® Glaze based on design, material, performance, technological characteristics and consensus standards.

Dreve Dentamid GmbH

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4ADr:ReinerAitmann

(Head of Quality Management / Quality Control / Regulatory Affairs
& Safety Representative for Medical Devices)



VDDI
Dental Solutions
German Manufacturers

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Keep it simple & smart

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Dreve Dentamid GmbH
Max-Planck-StraBe 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