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
Plaquix
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.

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."
510(k) Summary

Submitter: Dreve Dentamid GmbH
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Establishment Reg. No. 1000486347

Contact: Dr. Reiner Altmann
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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
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<thead>
<tr>
<th>Bank</th>
<th>Kto.-Nr.</th>
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<th>BIC</th>
<th>IBAN</th>
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</tbody>
</table>
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:

<table>
<thead>
<tr>
<th>Comparable Parameter</th>
<th>Dental sealing lacquers (NanoVarnish, Plaquit, Lightpaint on Surface)</th>
<th>VITA ENAMIC® Glaze K123761</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>Dental sealing lacquer for coating resin temporaries</td>
<td>Sealing lacquer for the surface characterization of dental restorations.</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>Varnish for final coating for resin temporaries to produce a smooth and shiny surface.</td>
<td>VITA ENAMIC® Stains are indicated for shade customization and characterization of the surface of dental restorations made of hybrid ceramic resin and resin materials. The Glaze material provided in the Stains set is the final coating providing protection of the stains from abrasion wear.</td>
</tr>
</tbody>
</table>
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/Processing time | < 1 min. | < 1 min. |
| Curing time | approx. 3 - 5 min. | approx. 3 min. |
| Temperature | Room temperature | Room temperature |
| Shelf life | 2 years | 2 years |

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.
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

4ADr:Reiner Aitmann
(Head of Quality Management / Quality Control / Regulatory Affairs & Safety Representative for Medical Devices)