



September 13, 2019

Nobio Ltd.
% Shoshana Friedman
Senior Consultant
ProMedoss, Inc.
3521 Hatwynn Rd.
Charlotte, North Carolina 28269

Re: K182921
Trade/Device Name: Infinix Universal Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: June 13, 2019
Received: June 18, 2019

Dear Shoshana Friedman:

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,

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

Indications for Use

510(k) Number (if known)

K182921

Device Name

Infinix™ Universal Composite

Indications for Use (Describe)

The Infinix™ Universal Composite is indicated for:

- Restorations in the posterior region (Class I and II)
- Anterior restorations (Class III, IV)
- Class V restorations (cervical caries, root erosion, wedge-shaped defects)
- Veneering of discolored anterior teeth
- Splinting of mobile teeth
- Extended fissure sealing in molars and premolars
- Repair of composite/ceramic veneers

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
[as required by section 807.92(c)]
Infinix™ Universal Composite
510(k) Number K183921

5.1 SUBMITTER

Applicant's Name:

Nobio Ltd.
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Contact Person:

Shoshana (Shosh) Friedman
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Phone: 704-430-8695
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Date Prepared:

June 12, 2019

5.2 DEVICE

Trade Name:

Infinix™ Universal Composite

Classification: **Name:** Material, Tooth Shade, Resin

Product Code: EBF

Regulation No: 872.3690

Class: 2

Review Panel: Dental

5.3 PREDICATE DEVICE

Tetric EvoCeram®, manufactured by Ivoclar Vivadent, cleared under K042819 is the primary predicate device.

Additionally, we are using the following reference devices as examples of FDA-cleared devices that incorporate quaternary ammonium in their formulation:

- Infinix™ Flowable Composite cleared under K182580.
- Clearfil Protect Bond cleared under K033938
- Orthodontic Acrylic cleared under K141439 and Orthodontic Acrylic 2 cleared under K163482.

5.4 DEVICE DESCRIPTION

Infinix™ Universal Composite is a packable (high viscosity) dental composite filling material, intended for direct anterior and posterior restorations, class V restorations, veneering of discolored anterior teeth, and repair of composite/ceramic veneers. The resin matrix of the Infinix™ Universal Composite contains Urethane dimethacrylate (UDMA), Bisphenol-a glycidyl dimethacrylate (Bis-GMA) and triethylene glycol dimethacrylate (TEGDMA).

The inorganic filler of the Infinix™ Universal Composite is a mix of particles of alumino-silicate-based glasses, silica dioxide and pigments. A small percentage of the silica-based filler particles are covalently bound to quaternary ammonium residues (QASi), added to maintain the integrity of the restoration.

Note: *“Clinical studies demonstrating that the presence of QASi in this device improves clinical outcomes have not been conducted”.*

The Infinix™ Universal Composite is provided in syringes (4 g) and in single-dose capsules (0.2 g) and is available in five shades (A1, A2, A3, B1 and translucent).

5.5 INDICATIONS FOR USE

Infinix™ Universal Composite is indicated for use in:

- Restorations in the posterior region (Class I and II)
- Anterior restorations (Class III, IV)
- Class V restorations (cervical caries, root erosion, wedge-shaped defects)
- Veneering of discolored anterior teeth
- Splinting of mobile teeth
- Extended fissure sealing in molars and premolars
- Repair of composite/ceramic veneers

5.6 SUBSTANTIAL EQUIVALENCE

The Infinix™ Universal Composite has the same indications as the Tetric EvoCeram® by Ivoclar Vivadent.

The technological characteristics of the Infinix™ Universal Composite are substantially equivalent to these of the predicate device, the Infinix™ Flowable Composite and other methacrylate-based products currently on the market. Table 5-1 below shows a comparison of Infinix™ Universal Composite and the predicate device.

Table 5-1: Comparison of Infinix™ Universal Composite and Tetric EvoCeram®

Feature	Infinix™ Universal Composite	Tetric EvoCeram®
510(k) Number	K182921	K042819
Classification	EBF	EBF
Indications	• Restorations in the posterior region (Classes I and II) • Anterior restorations (Classes III, IV) • Class V restorations (cervical caries, root erosion, wedge-shaped defects) • Veneering of discolored anterior teeth • Splinting of mobile teeth • Extended fissure sealing in molars and premolars • Repair of composite/ceramic veneers	• Restoration of deciduous teeth • Restorations in the posterior region (Classes I and II) • Anterior restorations (Classes III, IV) • Class V restorations (cervical caries, root erosion, wedge-shaped defects) • Veneering of discolored anterior teeth • Splinting of mobile teeth • Extended fissure sealing in molars and premolars • Repair of composite/ceramic veneers • Build-ups for transparent, removable, Invisalign® orthodontic retainers
Composition	Methacrylate resins, photo-initiators, inorganic fillers	Methacrylate resins, photo-initiators, inorganic fillers
Packaging	Syringe and single-dose capsule	Syringe and single-dose capsule
Flexural Strength	ISO 4049:2009	ISO 4049:2009
Intensity for curing	≥550 mW/cm ²	500 -1000 mW/cm ²
Wavelength for curing	430-490 nm	400-500 nm
Curing time	20 sec.	10 -20 sec* depending on shade
Radio-opacity	ISO 4049: 2009	ISO 4049: 2009
Depth of Cure	ISO 4049: 2009	ISO 4049: 2009
Water Sorption	ISO 4049:2009	ISO 4049:2009
Water Solubility	ISO 4049:2009	ISO 4049:2009
Spontaneous Polymerization Sensitivity at Ambient Light	ISO 4049:2009	ISO 4049:2009

5.7 PERFORMANCE DATA

Non-Clinical Performance Testing:

Non-clinical and biological testing was completed to assess the performance and biocompatibility of the Infinix™ Universal Composite and to support substantial equivalence. The data provided in this 510(k) submission shows that the composite is biocompatible based on the biocompatibility assessment conducted as per ISO 10993 and ISO 7405 and performs as intended based on the bench testing per ISO 4049 and FDA guidance document “Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions”. The list of these tests is provided in Table 5-2.

Table 5-2: List of Tests Completed on Infinix™ Universal Composite

Biocompatibility
Cytotoxicity
Oral Mucosal Irritation Test
Acute Systemic Toxicity
Material Mediated Pyrogenicity
Bacterial Reverse Mutation
Mouse Lymphoma Assay
Biological Risk Assessment
Bench Testing
Flexural strength
Elastic modulus
Compression strength
Shade and color stability
Polymerization conversion degree
Viscosity
Spontaneous polymerization sensitivity at ambient light
Water solubility
Water sorption
Depth of cure
Radio-opacity
Knoop hardness
Preservation of surface integrity

Animal and Clinical Performance Testing:

Animal and clinical performance data was not included.

5.8 CONCLUSION

Nobio Ltd. believes that Infinix™ Universal Composite is substantially equivalent to the Tetric EvoCeram®, the Infinix™ Flowable Composite and other legally marketed products. It does not introduce new indications for use, has similar technological characteristics and does not introduce any new safety or effectiveness concerns.