August 14, 2020

Nobio Ltd.
℅ Shoshan (Shosh) Friedman
Senior Regulatory Consultant
ProMedoss, Inc.
3521 Hatwynn Rd.
Charlotte, North Carolina 28269

Re: K201010
Trade/Device Name: Infinix Universal Composite, Infinix Flowable Composite, Infinix Bulk Fill Flow Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: April 14, 2020
Received: April 17, 2020

Dear Shoshan (Shosh) 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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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)*
K201010

Device Name
Infinix™ Universal Composite

Indications for Use *(Describe)*

- 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

The addition of the QASi particles to the Infinix™ Universal Composite reduces demineralization, which is part of the caries-formation process.

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."

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)*
K201010

Device Name
Infinix™ Flowable Composite

Indications for Use *(Describe)*

- Class III and V restorations
- Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations)
- As base/liner under direct or indirect restorations
- Repair of small defects in aesthetic indirect restorations
- Pit and fissure sealant
- Blocking out of undercuts
- Repair of resin and acrylic temporary materials

The addition of the QASi particles to the Infinix™ Flowable Composite reduces demineralization, which is part of the caries-formation process.

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."

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)*
K201010

Device Name
Infinix™ Bulk Fill Flow Composite

Indications for Use *(Describe)*
• Base under Class I and II direct restorations
• Liner under direct restorative materials
• Pit and fissure sealant
• Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations)
• Class III and V restorations
• Blocking out of undercuts
• Repair of small enamel defects
• Repair of small defects in esthetic indirect restorations
• Repair of resin and acrylic temporary materials
• As a core build-up where at least half the coronal tooth structure is remaining to provide structural support for the crown
The addition of the QASi particles to the Infinix™ Bulk Fill Flow Composite reduces demineralization, which is part of the caries-formation process.

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

[as required by section 807.92(c)]

Infinix™ Family of Dental Composites

510(k) Number K201010

5.1 SUBMITTER

Applicant's Name:
Nobio Ltd.
8 Hamatechet St.
POB 50502
Kadima, Israel 6092000
Phone: +972-3-9059966

Contact Person:
Shoshana (Shosh) Friedman
Senior Regulatory Consultant
3521 Hatwynn Rd.
Charlotte, NC 28269
Phone: 704-430-8695
s.friedman@promedoss.com

Date Prepared:
August 7, 2020

5.2 DEVICE

Trade Name:
Infinix™ Family of Dental Composites which includes:

- Infinix™ Universal Composite
- Infinix™ Flowable Composite
- Infinix™ Bulk Fill Flow Composite

Classification: **Name:** Material, Tooth Shade, Resin
Product Code: EBF
Regulation No: 872.3690
Class: 2
Review Panel: Dental

5.3 PREDICATE DEVICES

- K182921 Infinix™ Universal Composite (previously called Novidia™ Universal Composite)

- K182580 Infinix™ Flowable Composite (previously called Novidia™ Flowable Composite)
- K182714 Infinix™ Bulk Fill Flow Composite (previously called Novidia™ Bulk Fill Flow Composite)

5.4 DEVICE DESCRIPTION

Composite restorations are performed with two main components: a resin-based composite for filling the prepared tooth cavity and the bonding system which is applied to the cavity before the placement of the composite filling material.
The composites are resin based and the proportion of the inorganic filler material is the main differentiator among the composite materials.
The Infinix™ Family of Dental Composites include the following light-cured, resin-based composite materials:

- Universal Composite
- Flowable Composite
- Bulk Fill Flow Composite

There are no changes to the formulation, manufacturing processes, and packaging of the three composites submitted under K182921, K182714, and K182580.

Some of the silica-based filler particles (max 1.2% wt/wt of the total formulation) contained in all the Infinix™ composites are decorated with quaternary ammonium functional groups that are covalently bound to the filler particles' silica core via a silane linker (herein referred to as "QASi"). Following light induced polymerization, QASi particles (produced by Nobio) remain permanently entrapped within the composite restoration and destroy microorganisms by contact. As the cell membrane of microorganisms is negatively charged and the QASi particles have strong positive charges, microorganisms are electrostatically attracted to the positively charged cured material's surface resulting in disruption of their cell membrane and immediate microbial lysis.

5.5 INDICATIONS FOR USE

The indications for Use of the Infinix™ Family of Dental Composites is substantially similar to these of their predicate devices with the exception of the inclusion of an antimicrobial claim based on data collected from in situ clinical study.

Subject Devices	Predicate Devices
Infinix™ Universal Composite • 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	**Infinix™ Universal Composite (K182921)** • 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 The addition of the QASi particles to the Infinix™ Universal Composite reduces demineralization, which is part of the caries-formation process.	• Splinting of mobile teeth • Extended fissure sealing in molars and premolars • Repair of composite/ceramic veneers
Infinix™ Flowable Composite • Class III and V restorations • Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations) • As base/liner under direct or indirect restorations • Repair of small defects in esthetic indirect restorations • Pit and fissure sealant • Blocking out of undercuts • Repair of resin and acrylic temporary materials The addition of the QASi particles to the Infinix™ Flowable Composite reduces demineralization, which is part of the caries-formation process.	**Infinix™ Flowable Composite (K182580)** • Class III and V restorations • Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations) • As base/liner under direct or indirect restorations • Repair of small defects in esthetic indirect restorations • Pit and fissure sealant • Blocking out of undercuts • Repair of resin and acrylic temporary materials
Infinix™ Bulk Fill Flow Composite • Base under Class I and II direct restorations • Liner under direct restorative materials • Pit and fissure sealant • Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations) • Class III and V restorations • Blocking out of undercuts • Repair of small enamel defects • Repair of small defects in esthetic indirect restorations • Repair of resin and acrylic temporary materials • As a core build-up where at least half the coronal tooth structure is remaining	**Infinix™ Bulk Fill Flow Composite (K182714)** • Base under Class I and II direct restorations • Liner under direct restorative materials • Pit and fissure sealant • Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations) • Class III and V restorations • Blocking out of undercuts • Repair of small enamel defects • Repair of small defects in esthetic indirect restorations • Repair of resin and acrylic temporary materials • As a core build-up where at least half the coronal tooth structure is remaining

to provide structural support for the crown The addition of the QASi particles to the Infinix™ Bulk Fill Flow Composite reduces demineralization, which is part of the caries-formation process.	to provide structural support for the crown

5.6 SUBSTANTIAL EQUIVALENCE

The Infinix™ Universal Composite, Infinix™ Flowable Composite, and Infinix™ Bulk Fill Flow Composite have the exact same formulation, manufacturing processes, and packaging as the three composites submitted under K182921, K182714, and K182580. The only differences implemented in this submission are:

1) Removal from the Instructions for Use the statement "*Clinical studies have not been conducted to demonstrate that the presence of QASi in this device results in improved clinical outcomes*" that was requested by the Agency in the previous 510(k) submissions; and
2) Addition of the following statement to the intended use of each composite: "The addition of the QASi particles to the {*composite name*} reduces demineralization, which is part of the caries-formation process."

5.7 PERFORMANCE DATA

Non-Clinical Performance Testing:

All non-clinical and biological testing submitted in K182921, K182714, and K182580 apply to this submission as no changes have been implemented in the formulation, manufacturing processes, and packaging.

Clinical Performance Testing:

An in-situ clinical study comparing Infinix™ Universal Composite to a widely used, similar composite without antibacterial particles was conducted at the School of Dentistry, UCSF (San Francisco, CA). Subjects wearing lower partial dentures with acrylic flanges on both sides of the mouth who met the eligibility criteria were recruited. On each side of the denture an enamel slab was placed next to a composite, separated by a tiny gap. On one side of the denture the composite was Nobio's Infinix Universal Composite ("Nobio group"), on the other side a widely used, similar composite without antibacterial particles served as control material ("control group"). Enamel slab and composite were recessed into the flange, allowing microbial plaque to accumulate on top of it and especially in the gap. After wearing the dentures for four weeks with the slabs, decalcification (mineral loss) in the enamel slabs adjacent to the gap were determined by cross-section microhardness testing in the laboratory. Average mineral loss was calculated for the Nobio group and the control group, and difference tested for statistical significance.

A total of 25 subjects, 17 males and 8 females, were recruited having an average age of 63.7 ± 14.1 years (range 33.66 to 80.98 years) and their ethnicity included 12 subjects

(48%) white and 13 subjects (52%) non-white (7 Black, 3 Hispanic, 2 Asian, and 1 Native American). The subjects wore the gap models in average for 27.9 ± 1.2 days (range 26 to 31 days), thus meeting the targeted 4-week in situ wearing period. The average mineral loss ΔZ (vol% x μm) in enamel slabs facing the control composite was 730.8 ± 558 while the average mineral loss ΔZ in enamel slabs facing the Nobio composite with antibacterial particles was 233.8 ± 330.9. The two-tailed, paired t-test determined the significance level for a difference as $P<0.0001$, which demonstrates that the difference in average mineral loss between control and Nobio sides is statistically significant. Analysis of the individual ΔZ mineral losses for the control side and the Nobio side for all evaluated subjects showed that in all cases the ΔZ mineral loss for the Nobio side was lower than the control side (-268 to 862 in Nobio side vs. -7 to 2,081 in the control side).

5.8 CONCLUSION

Nobio Ltd. believes that the Infinix™ Family of Dental Composites, which includes the Infinix™ Universal Composite, Infinix™ Flowable Composite, and Infinix™ Bulk Fill Flow Composite, are substantially equivalent to their predicate devices without introducing any new safety or effectiveness concerns and, as shown in the in-situ clinical study, the addition of the QASi particles to these composites reduces demineralization, which is part of the carries-formation process.