July 12, 2019

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

Re: K182714
Trade/Device Name: Novidia™ Bulk Fill Flow Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: June 11, 2019
Received: June 12, 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,

for Srinivas Nandkumar, Ph.D.
Acting Assistant 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)*

K182714

Device Name

Novidia™ Bulk Fill Flow Composite

Indications for Use *(Describe)*

The Novidia™ Bulk Fill Flow Composite is indicated for:
1. Base under Class I and II direct restorations
2. Liner under direct restorative materials
3. Pit and fissure sealant
4. Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations)
5. Class III and V restorations
6. Blocking out of undercuts
7. Repair of small enamel defects
8. Repair of small defects in esthetic indirect restorations
9. Repair of resin and acrylic temporary materials
10. As a core build-up where at least half the coronal tooth structure is remaining to provide structural support for the crown

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.

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510(K) SUMMARY

[as required by section 807.92(c)]

Novidia™ Bulk Fill Flow Composite

510(k) Number K182714

5.1 SUBMITTER

Applicant's Name:
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Phone: +972 3 9059966

Contact Person:
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Charlotte, NC 28269
Phone: 704-430-8695
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Date Prepared:
July 12, 2019

5.2 DEVICE

Trade Name:
Novidia™ Bulk Fill Flow Composite

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

5.3 PREDICATE DEVICE

Filtek™ Bulk Fill Flowable Restorative, manufactured by 3M ESPE Dental Products, cleared under K120453 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:

- Clearfil Protect Bond cleared under K033938
- Orthodontic Acrylic cleared under K141439 and Orthodontic Acrylic 2 cleared under K163482.

5.4 DEVICE DESCRIPTION

Novidia™ Bulk Fill Flow Composite is a low viscosity, visible-light activated, radiopaque, flowable composite indicated for minimally invasive cavity preparations as well as various other indications.
The resin matrix of the Novidia™ Bulk Fill Flow Composite contains Urethane dimethacrylate (UDMA), Bisphenol-a glycidyl dimethacrylate (Bis-GMA) and triethylene glycol dimethacrylate (TEGDMA).

The inorganic filler of the Novidia™ Bulk Fill Flow 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 Novidia™ Bulk Fill Flow Composite is provided in syringes (2 g) and in single-dose capsules (0.2 g) and is available in two shades (A2 and A3).

5.5 INDICATIONS FOR USE

Novidia™ Bulk Fill Flow Composite is indicated for:

1. Base under Class I and II direct restorations
2. Liner under direct restorative materials
3. Pit and fissure sealant
4. Restoration of minimally invasive cavity preparations (including small, non-stress-bearing occlusal restorations)
5. Class III and V restorations
6. Blocking out of undercuts
7. Repair of small enamel defects
8. Repair of small defects in esthetic indirect restorations
9. Repair of resin and acrylic temporary materials
10. As a core build-up where at least half the coronal tooth structure is remaining to provide structural support for the crown

5.6 SUBSTANTIAL EQUIVALENCE

The Novidia™ Bulk Fill Flow Composite has the same indications as the Filtek™ Bulk Fill Flowable Restorative.

The technological characteristics of the Novidia™ Bulk Fill Flow Composite are substantially equivalent to these of the predicate device and other methacrylate-based products currently on the market. Table 5-1 below shows a comparison of Novidia™ Bulk Fill Flow Composite and the predicate device.

Table 5-1: Comparison of Novidia™ Bulk Fill Flow Composite and Filtek™ Bulk Fill Flowable Restorative

Feature	Novidia™ Bulk Fill Flow Composite	Filtek Bulk Fill Flowable Restorative	Comparison
510(k) Number	K182714	K120453	NA
Classification	EBF	EBF	Same
Indications	• Base under Class I and II direct restoration • 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	• 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 • Undercut blockout • 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	Same
Composition	Methacrylate resins, photo-initiators, inorganic fillers	Methacrylate resins, photo- initiators, inorganic fillers	Similar
Packaging	Syringe and single-dose capsule	Syringe and ampule	Same
Flexural Strength	ISO 4049:2009	ISO 4049:2009	Both met acceptance criteria of ≥80 MPa
Intensity for curing	≥550 mW/cm^2	400 -1000 mW/cm^2	Similar
Wavelength for curing	430-490 nm	400-500 nm	Same
Curing time	20 sec.	Opaque shades 40 sec; All other shades 20 sec.	Same

Radio-opacity	ISO 4049: 2009	ISO 4049: 2009	Both met acceptance criteria of >1.0 mm Al
Depth of Cure	ISO 4049: 2009	ISO 4049: 2009	Both met acceptance criteria of ≥2mm at an intensity of ≥550 mW/cm^2 for 20 seconds
Water Sorption	ISO 4049:2009	ISO 4049:2009	Both met acceptance criteria of ≤ 40µg/mm^3
Water Solubility	ISO 4049:2009	ISO 4049:2009	Both met acceptance criteria of ≤7.5 µg/mm^3
Spontaneous Polymerization Sensitivity at Ambient Light	ISO 4049:2009	ISO 4049:2009	Both met acceptance criteria of 60±5 sec. (physically homogenous by visual inspection)

5.7 PERFORMANCE DATA

Non-Clinical Performance Testing:

Non-clinical and biological testing was completed to assess the performance and biocompatibility of the Novidia™ Bulk Fill Flow 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 Novidia™ Bulk Fill Flow 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 Novidia™ Bulk Fill Flow Composite is substantially equivalent to the Filtek™ Bulk Fill Flow Restorative and other legally marketed products.