

## K201010 Infinix Universal Composite, Infinix Flowable Composite, Infinix Bulk Fill Flow Composite

Aug 14, 2020  
119 days to decision

K201010 · Product code: EBF · Dental  
Source: <https://www.510kdatabase.net/k201010/>

### SUBMISSION DETAILS

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Material, Tooth Shade, Resin (EBF) |
| Date received         | Apr 17, 2020                       |
| Decision date         | Aug 14, 2020                       |
| Days to decision      | 119 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

### APPLICANT

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Nobio , Ltd.</b>                   |
| Location       | Petach Tikva, IL                      |
| Contact        | Galit Gershon                         |
| 510(k) history | 5 submissions · 5 cleared · 2019-2020 |

### REGULATORY CONSULTANT

|                 |                          |
|-----------------|--------------------------|
| Consulting firm | <b>ProMedoss, Inc.</b>   |
| Contact         | Shoshan (Shosh) Friedman |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

### CLINICAL EVIDENCE - NCT04059250

#### Nobio Clinical Study - Demineralization Prevention With a New Antibacterial Restorative Composite

|                   |   |
|-------------------|---|
| Status            | Completed                                       |
| Enrollment        | 25 patients (actual)                            |
| Study sites       | 1 site  |
| Condition studied | Dental Caries; Denture, Partial, Removable      |
| Primary purpose   | Prevention                                      |
| Study type        | Interventional                                  |
| Study design      | Parallel  |
| Masking           | Double blind                                    |
| Completion date   | Mar 10, 2020                                    |
| Sponsor           | University of California, San Francisco (Other) |

#### Primary outcome

Mineral Loss ?Z

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04059250](https://clinicaltrials.gov/study/NCT04059250)