

K153191 Calcium BridgeFeb 26, 2016
115 days to decisionK153191 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k153191/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Material, Tooth Shade, Resin (EBF) |
| Date received | Nov 3, 2015 |
| Decision date | Feb 26, 2016 |
| Days to decision | 115 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Denali Corporation |
| Location | Hanover, MA, US |
| Contact | Jan G Stannard |
| 510(k) history | 9 submissions · 9 cleared · 2007-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153191/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 3, 2026