

**K192007 TheraBase, TheraBase Ca**Mar 17, 2020  
232 days to decisionK192007 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k192007/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Jul 29, 2019
Decision date	Mar 17, 2020
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Bisco, Inc.</b>
Location	Mchenry, IL, US
Contact	Diana Vu
510(k) history	88 submissions · 88 cleared · 1984-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192007/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026