

**K211237 UltraTemp Rez II**Jul 13, 2021  
78 days to decisionK211237 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k211237/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Apr 26, 2021
Decision date	Jul 13, 2021
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ultradent Products, Inc.</b>
Location	Salt Lake City, UT, US
Contact	Shawn L. Quigley
Website	<a href="https://www.ultradent.com">https://www.ultradent.com</a>
510(k) history	103 submissions · 103 cleared · 1992-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211237/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026