

**K002989 PROCLUDE**Dec 14, 2000  
80 days to decisionK002989 · Product code: **EJR** · Dental  
Source: <https://www.510kdatabase.net/k002989/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Polishing, Abrasive, Oral Cavity (EJR)
Date received	Sep 25, 2000
Decision date	Dec 14, 2000
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ortek Therapeutics, Inc.</b>
Location	New York, NY, US
Contact	JULES T MITCHEL
510(k) history	3 submissions · 3 cleared · 2000-2017

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k002989/> 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 31, 2026