

**K003482 PROCLUDE-SENSITIVE**Feb 1, 2001  
84 days to decisionK003482 · Product code: **LBH** · Dental  
Source: <https://www.510kdatabase.net/k003482/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Nov 9, 2000
Decision date	Feb 1, 2001
Days to decision	84 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/k003482/> 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