

**K170822 Electronic Caries Detector**Sep 11, 2017  
175 days to decisionK170822 · Product code: **NBL** · Dental  
Source: <https://www.510kdatabase.net/k170822/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Fluorescence Caries Detection (NBL)
Date received	Mar 20, 2017
Decision date	Sep 11, 2017
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170822/> 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