

**K153549 OSSIX VOLUMAX**Aug 4, 2016  
237 days to decisionK153549 · Product code: **NPL** · Dental  
Source: <https://www.510kdatabase.net/k153549/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Dec 11, 2015
Decision date	Aug 4, 2016
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Datum Dental, Ltd.</b>
Location	Lod, IL
Contact	Arie Goldlust
510(k) history	4 submissions · 4 cleared · 2016-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153549/> 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 27, 2026