

**K200817 URIS OMNI Narrow System & Prosthetic**Oct 7, 2020  
191 days to decisionK200817 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k200817/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 30, 2020
Decision date	Oct 7, 2020
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Truabutment, Inc.</b>
Location	Anaheim, CA, US
Contact	Eunjin Jang
510(k) history	15 submissions · 15 cleared · 2018-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200817/> 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 26, 2026