

**K242944 Leone Orthodontic Implant TAD (Temporary Anchorage Device)**Jun 19, 2025  
267 days to decisionK242944 · Product code: **OAT** · Dental  
Source: <https://www.510kdatabase.net/k242944/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Orthodontic (OAT)
Date received	Sep 25, 2024
Decision date	Jun 19, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Leone S.P.A.</b>
Location	Irvine, CA, US
Contact	Martina Corsani
510(k) history	4 submissions · 4 cleared · 2006-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>ProMedic, LLC</b>
Contact	Paul Dryden

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242944/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026