

**K161989 PREMIUM Implant Systems SHELTA Implant Systems**Feb 1, 2018  
562 days to decisionK161989 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k161989/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jul 19, 2016
Decision date	Feb 1, 2018
Days to decision	562 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sweden &amp; Martina S.P.A.</b>
Location	Due Carrare, IT
Contact	Alessia Pezzato
510(k) history	8 submissions · 8 cleared · 2015-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161989/> 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