

**K161957 W&H Implantmed SI-1015 incl. Accessories**Nov 23, 2016  
128 days to decisionK161957 · Product code: **EBW** · Dental  
Source: <https://www.510kdatabase.net/k161957/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Foot, Handpiece And Cord (EBW)
Date received	Jul 18, 2016
Decision date	Nov 23, 2016
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>W&amp;H Dentalwerk Burmoos GmbH</b>
Location	Buermoos, AT
Contact	ANJA LINDNER
510(k) history	2 submissions · 2 cleared · 2016-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161957/> 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 June 1, 2026