

**K153521 IH Implant System**Oct 14, 2016  
311 days to decisionK153521 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k153521/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 8, 2015
Decision date	Oct 14, 2016
Days to decision	311 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sewonmedix, Inc.</b>
Location	Busan, KR
Contact	Bum-keun Park
510(k) history	2 submissions · 2 cleared · 2016-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153521/> 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