

**K231395 INNO SLA Submerged Narrow Implant System**Oct 18, 2023  
156 days to decisionK231395 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k231395/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	May 15, 2023
Decision date	Oct 18, 2023
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cowellmedi Co., Ltd.</b>
Location	Newington, NH, US
Contact	Haejun Lee
510(k) history	14 submissions · 14 cleared · 2004-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231395/> 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 13, 2026