

**K050635 ALLFIM IMPLANT SYSTEMS**Jul 28, 2005  
119 days to decisionK050635 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k050635/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 31, 2005
Decision date	Jul 28, 2005
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cowellmedi Co., Ltd.</b>
Location	Newington, NH, US
Contact	DAE KYU CHANG
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/k050635/> 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 26, 2026