

**K181138 IS-III active System**Oct 3, 2018  
156 days to decisionK181138 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k181138/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 30, 2018
Decision date	Oct 3, 2018
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neobiotech Co., Ltd.</b>
Location	Santa Fe Springs, CA, US
Contact	Young-Ku Heo
510(k) history	17 submissions · 17 cleared · 2004-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181138/> 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