

**K190849 IS-III active System\_S-narrow Type**Aug 14, 2019  
135 days to decisionK190849 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k190849/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 1, 2019
Decision date	Aug 14, 2019
Days to decision	135 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/k190849/> 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 25, 2026