

**K183242 ET IV SA Dental Implants**May 21, 2019  
181 days to decisionK183242 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k183242/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Nov 21, 2018
Decision date	May 21, 2019
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hiossen, Inc.</b>
Location	Fariless Hills, PA, US
Contact	Peter Lee
510(k) history	25 submissions · 25 cleared · 2009-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183242/> 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 14, 2026