

**K112532 ET II BIO-SA FIXTURE SYSTEM**Aug 6, 2012  
341 days to decisionK112532 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k112532/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 31, 2011
Decision date	Aug 6, 2012
Days to decision	341 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hiossen, Inc.</b>
Location	Fariless Hills, PA, US
Contact	PATRICK LIM
510(k) history	26 submissions · 26 cleared · 2009-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112532/> 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 June 14, 2026