

**K240232 EK D3.3 and Ultra Wide Implants**Sep 13, 2024  
228 days to decisionK240232 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k240232/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 29, 2024
Decision date	Sep 13, 2024
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	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/k240232/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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