

K241003 HIOSSEN Pre-milled Abutment (ET Pre-milled Abutment & EK Pre-milled Abutment)Jan 8, 2025
271 days to decisionK241003 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k241003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Apr 12, 2024
Decision date	Jan 8, 2025
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	IZiel Healthcare
Contact	Ankur Naik

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241003/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026