FDA 510(k) Premarket Notification

CLEARED

K241003 HIOSSEN Pre-milled Abutment (ET Pre-milled Abutment & EK Pre-milled Abutment)

Jan 8, 2025
271 days to decision

K241003 · 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