FDA 510(k) Premarket Notification

K250489 FP3D

CLEARED

May 20, 2025
90 days to decision

K250489 · Product code: **EBI** · Dental
Source: https://www.510kdatabase.net/k250489/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Feb 19, 2025
Decision date	May 20, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Keystone Industries**
Location	Gibbstown, NJ, US
Contact	Autumn McClure
510(k) history	3 submissions · 3 cleared · 2019-2025