

K233171 PF Keep

Nov 27, 2023
60 days to decision

K233171 · Product code: **EBI** · Dental
Source: <https://www.510kdatabase.net/k233171/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Sep 28, 2023
Decision date	Nov 27, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Cad Cam Keep Block

APPLICANT

Company	Clemde SA DE CV
Location	Mexico City, MX
Contact	Francisco Cabrera
Website	http://www.clemde.com/
510(k) history	2 submissions · 2 cleared · 2023-2025

Clemde SA DE CV is a Mexican manufacturer and distributor of materials and systems for dental technicians. The company operates with a manufacturing facility in Mexico City, MX. Founded in 1999, Clemde has built a portfolio of over 200 products serving the global dental market. The company has received FDA 510(k) clearances from total submissions, with all submissions focused on Dental devices. First clearance was in 2023, with the most recent clearance in 2025, demonstrating active ongoing regulatory engagement. Clemde’s cleared Dental devices include systems for flexibl...