

**K242897 Partial Flex**Jun 3, 2025  
253 days to decisionK242897 · Product code: **EBI** · Dental  
Source: <https://www.510kdatabase.net/k242897/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Sep 23, 2024
Decision date	Jun 3, 2025
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Clemde SA DE CV</b>
Location	Mexico City, MX
Contact	Cabrera Francisco
Website	<a href="http://www.clemde.com/">http://www.clemde.com/</a>
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...