

K213994 Flexible BlockMar 4, 2022
73 days to decisionK213994 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k213994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Dec 21, 2021
Decision date	Mar 4, 2022
Days to decision	73 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Huge Dental Material Corporation
Location	Rizhao City, CN
Contact	Maggie Zheng
510(k) history	8 submissions · 8 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213994/> 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 25, 2026