

K801237 REIGNING CROWN-BRIDGE/POLYCARB. RESINJun 9, 1980
13 days to decisionK801237 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k801237/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	May 27, 1980
Decision date	Jun 9, 1980
Days to decision	13 days
Third-party review	No

APPLICANT

Company	Oki Shiks USA , Ltd.
Location	Mchenry, IL, US
510(k) history	9 submissions · 9 cleared · 1980-1982

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k801237/> 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 July 6, 2026