

**K875344 HERAEUS' HERAGAM 48, NON GAMMA 2 DEN.
AMAL. ALLOY**Mar 18, 1988
79 days to decisionK875344 · Product code: EJJ · Dental
Source: <https://www.510kdatabase.net/k875344/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alloy, Amalgam (EJJ)
Date received	Dec 30, 1987
Decision date	Mar 18, 1988
Days to decision	79 days
Third-party review	No

APPLICANT

Company	Kulzer, Inc.
Location	Mchenry, IL, US
Contact	BAUER, PHD
510(k) history	31 submissions · 31 cleared · 1981-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k875344/>; 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 4, 2026