

K854106 BAYSILEXMar 17, 1986
160 days to decisionK854106 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k854106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Oct 8, 1985
Decision date	Mar 17, 1986
Days to decision	160 days
Third-party review	No

APPLICANT

Company	Cutter Laboratories, Inc.
Location	Mchenry, IL, US
Contact	STEVEN J OJALA
Website	https://www.bayer.com
510(k) history	39 submissions · 39 cleared · 1976-1986

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k854106/> 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 22, 2026