

K013236 LUXABITEOct 17, 2001
19 days to decisionK013236 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k013236/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Material, Impression (ELW)
Date received	Sep 28, 2001
Decision date	Oct 17, 2001
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dmg USA, Inc.
Location	Ayer, MA, US
Contact	PAMELA PAPINEAU
510(k) history	28 submissions · 28 cleared · 2000-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013236/> 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 1, 2026