

K010414 R & D DESIGNATION AP-035Mar 27, 2001
43 days to decisionK010414 · Product code: **EJT** · DentalSource: <https://www.510kdatabase.net/k010414/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Alloy, Gold-based Noble Metal (EJT)
Date received	Feb 12, 2001
Decision date	Mar 27, 2001
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jensen Industries, Inc.
Location	North Haven, CT, US
Contact	JOHN SLANSKI
510(k) history	17 submissions · 17 cleared · 1998-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010414/> 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 June 18, 2026