

K010044 COSMICFeb 9, 2001
35 days to decisionK010044 · Product code: **EJT** · DentalSource: <https://www.510kdatabase.net/k010044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alloy, Gold-based Noble Metal (EJT)
Date received	Jan 5, 2001
Decision date	Feb 9, 2001
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jeneric/Pentron, Inc.
Location	Wallingford, CT, US
Contact	ANNMARIE TENERO
510(k) history	78 submissions · 78 cleared · 1988-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010044/> 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 26, 2026