

K043496 SPACELINE EMCIA, MODEL CU580Feb 16, 2005
61 days to decisionK043496 · Product code: **EIA** · DentalSource: <https://www.510kdatabase.net/k043496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Dec 17, 2004
Decision date	Feb 16, 2005
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	J. Morita USA, Inc.
Location	Irvine, CA, US
Contact	KEITH A BARRITT
510(k) history	52 submissions · 52 cleared · 1988-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043496/> 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 14, 2026