

K983357 MUCOPREN SOFT RELINING SYSTEMNov 13, 1998
50 days to decisionK983357 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k983357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Sep 24, 1998
Decision date	Nov 13, 1998
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roydent Dental Products, Inc.
Location	Rochester Hills, MI, US
Contact	DON LEROY
510(k) history	3 submissions · 3 cleared · 1996-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983357/> 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 2, 2026