

K964177 KROMALGIN IMPRESSION MATERIALDec 30, 1996
73 days to decisionK964177 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k964177/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Oct 18, 1996
Decision date	Dec 30, 1996
Days to decision	73 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	North American Orthodontic Laboratories, Inc.
Location	Gainesville, TX, US
Contact	MARGARET H CHRISTOPHERSON
510(k) history	1 submissions · 1 cleared · 1996-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964177/> 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 3, 2026