

K942666 ORTHALGENAT IMPRESSION MATERIALAug 10, 1994
65 days to decisionK942666 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k942666/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Jun 6, 1994
Decision date	Aug 10, 1994
Days to decision	65 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Dentaurum, Inc.
Location	Newtown, PA, US
Contact	JOHEN J ROTH
510(k) history	24 submissions · 24 cleared · 1991-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942666/> 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