

K811666 COLTENE COLTEX/COLTOFLAXJul 15, 1981
30 days to decisionK811666 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k811666/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Jun 15, 1981
Decision date	Jul 15, 1981
Days to decision	30 days
Third-party review	No

APPLICANT

Company	Coltene, Inc.
Location	Mchenry, IL, US
510(k) history	13 submissions · 13 cleared · 1981-1990

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k811666/> 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 4, 2026