

K011419 CAVEX COLORCHANGEJul 16, 2001
68 days to decisionK011419 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k011419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	May 9, 2001
Decision date	Jul 16, 2001
Days to decision	68 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cavex Holland BV
Location	Rw Haarlem (Holland), NL
Contact	RICHARD WOORTMAN
Website	https://www.cavex.nl
510(k) history	26 submissions · 26 cleared · 1998-2015

Cavex Holland BV is a dental device manufacturer based in Haarlem, Netherlands. Founded in 1908, the company develops and manufactures impression materials, whitening products, restorative materials, and related dental solutions for professionals and consumers. Cavex has received FDA 510(k) clearances from total submissions, with no denied submissions on record. All cleared devices fall within the dental category. The company's regulatory history spans from 1998 to 2015. Cavex is currently inactive in the FDA 510(k) system, with no new clearances in more than five years; ...
