

K152243 One Coat 7 UniversalDec 9, 2015
121 days to decisionK152243 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k152243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Aug 10, 2015
Decision date	Dec 9, 2015
Days to decision	121 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Coltene/Whaledent AG
Location	New York, NY, US
Contact	Silke Wallaschek
510(k) history	16 submissions · 16 cleared · 2005-2019

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