

K053619 COLORBITEMar 1, 2006
64 days to decisionK053619 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k053619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Dec 27, 2005
Decision date	Mar 1, 2006
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Zhermack S.P.A.
Location	Bend, OR, US
Contact	GERALD W SHIPPS
510(k) history	19 submissions · 19 cleared · 1996-2009

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