FDA 510(k) Premarket Notification

K960547 DIMENSION PENTA/DIMENSION GARANT L/POLYVINYL SILOXANE ADHESIVE

CLEARED

Mar 15, 1996
36 days to decision

K960547 · Product code: **ELW** · Dental
Source: https://www.510kdatabase.net/k960547/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Feb 8, 1996
Decision date	Mar 15, 1996
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Espe GmbH & Co. Kg.**
Location	Seefeld, DE
Contact	BARBARA WAGNER
510(k) history	17 submissions · 17 cleared · 1995-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k960547/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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