FDA 510(k) Premarket Notification

K913965 ESPE(R) -SIL

CLEARED

Dec 4, 1991
90 days to decision

K913965 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k913965/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Sep 5, 1991
Decision date	Dec 4, 1991
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Espe GmbH (Us)**
Location	Mchenry, IL, US
Contact	DR. A BRECHENMACHER
510(k) history	59 submissions · 57 cleared · 1977-1993