FDA 510(k) Premarket Notification

K003293 EXCITE DSC

CLEARED

Feb 6, 2001
109 days to decision

K003293 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k003293/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Oct 20, 2000
Decision date	Feb 6, 2001
Days to decision	109 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ivoclar North America, Inc.**
Location	Amherst, NY, US
Contact	ANDY GULATI
510(k) history	131 submissions · 131 cleared · 1989-2001