FDA 510(k) Premarket Notification

K990040 CLEARFIL SE BOND

CLEARED

Feb 4, 1999
29 days to decision

K990040 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k990040/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Jan 6, 1999
Decision date	Feb 4, 1999
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kuraray Co.**
Location	New York, NY, US
Contact	KOJI FUJITA
510(k) history	25 submissions · 25 cleared · 1985-1999

Kuraray Co. is a Japanese manufacturer of chemicals, fibers, and advanced materials. The company maintains a US presence through its New York office. Kuraray received FDA 510(k) clearances from total submissions, with all submissions focused on Dental devices. The company's regulatory activity spans from 1985 to 1999, establishing a historical record in dental bonding and restorative materials. The cleared devices reflect Kuraray's specialization in dental adhesive systems and bonding technologies. Products include resin cements, surface activators, and liner bond systems...