

K925383 PHOTO CLEARFIL OPAQUERJan 28, 1993
97 days to decisionK925383 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k925383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Oct 23, 1992
Decision date	Jan 28, 1993
Days to decision	97 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Kuraray Co.
Location	New York, NY, US
Contact	KYOICHIRO SHIBATANI
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...

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