

K882006 CLEARFIL PHOTO COREJun 13, 1988
31 days to decisionK882006 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k882006/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	May 13, 1988
Decision date	Jun 13, 1988
Days to decision	31 days
Third-party review	No

APPLICANT

Company	Kuraray Co.
Location	New York, NY, US
Contact	PAUL ROBERTS
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...
