

K951813 CARIES DETECTORJul 11, 1995
84 days to decisionK951813 · Product code: **LFC** · DentalSource: <https://www.510kdatabase.net/k951813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Caries Detection (LFC)
Date received	Apr 18, 1995
Decision date	Jul 11, 1995
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Kuraray Co.
Location	New York, NY, US
Contact	TERRY G MAHN
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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k951813/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 2, 2026