

K897027 TEETHMATE-AMar 14, 1990
86 days to decisionK897027 · Product code: **EBC** · Dental
Source: <https://www.510kdatabase.net/k897027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Dec 18, 1989
Decision date	Mar 14, 1990
Days to decision	86 days
Third-party review	No

APPLICANT

Company	Kuraray Co.
Location	New York, NY, US
Contact	SHUJI KAWAI
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...
