

**K012742 TEETHMATE F-1**Sep 14, 2001  
31 days to decisionK012742 · Product code: **EBC** · Dental  
Source: <https://www.510kdatabase.net/k012742/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Aug 14, 2001
Decision date	Sep 14, 2001
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Kuraray Medical, Inc.</b>
Location	New York, NY, US
Contact	MASAYA SASAKI
510(k) history	42 submissions · 42 cleared · 2001-2012

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012742/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 15, 2026