

K010935 BRITESMILE BARRIER MATERIALSep 5, 2001
161 days to decisionK010935 · Product code: **EIE** · DentalSource: <https://www.510kdatabase.net/k010935/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dam, Rubber (EIE)
Date received	Mar 28, 2001
Decision date	Sep 5, 2001
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Britesmile, Inc.
Location	North Attleboro, MA, US
Contact	SHEILA HEMEON-HEYER
510(k) history	2 submissions · 2 cleared · 2001-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010935/> 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 1, 2026