

K071158 AURALAY PIT & FISSURE SEALANTJun 5, 2007
41 days to decisionK071158 · Product code: **EBC** · Dental
Source: <https://www.510kdatabase.net/k071158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Apr 25, 2007
Decision date	Jun 5, 2007
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Denali Corporation
Location	Hanover, MA, US
Contact	JAN G STANNARD
510(k) history	9 submissions · 9 cleared · 2007-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071158/> 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 June 3, 2026