

K982564 DELTON FS DIRECT DELIVERY SYSTEMOct 6, 1998
75 days to decisionK982564 · Product code: **EBC** · Dental
Source: <https://www.510kdatabase.net/k982564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Jul 23, 1998
Decision date	Oct 6, 1998
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply Intl.
Location	Walker, MI, US
Contact	P.JEFFERY LEHN
510(k) history	279 submissions · 279 cleared · 1976-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982564/> 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 May 19, 2026