FDA 510(k) Premarket Notification

K190998 BA Pit & Fissure Sealant

CLEARED

Nov 8, 2019
206 days to decision

K190998 · Product code: **EBC** · Dental
Source: https://www.510kdatabase.net/k190998/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Apr 16, 2019
Decision date	Nov 8, 2019
Days to decision	206 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Apex Dental Materials, Inc.**
Location	Schaumburg, IL, US
Contact	Scott Lamerand
510(k) history	15 submissions · 15 cleared · 2001-2019

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190998/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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