

K243254 Parkell Pit and Fissure SealantAug 8, 2025
297 days to decisionK243254 · Product code: **EBC** · Dental
Source: <https://www.510kdatabase.net/k243254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Oct 15, 2024
Decision date	Aug 8, 2025
Days to decision	297 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Parkell, Inc.
Location	Mchenry, IL, US
Contact	David Mott
510(k) history	53 submissions · 53 cleared · 1976-2025

REGULATORY CONSULTANT

Consulting firm	Fish & Richardson, P.C.
Contact	Keith Barritt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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