FDA 510(k) Premarket Notification

K190930 SmarTemp X1

CLEARED

Sep 5, 2019
148 days to decision

K190930 · Product code: **EBG** · Dental
Source: https://www.510kdatabase.net/k190930/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Apr 10, 2019
Decision date	Sep 5, 2019
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190930/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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