FDA 510(k) Premarket Notification

K102654 VERTEX RAPID SIMPLIFIED

CLEARED

Dec 3, 2010
80 days to decision

K102654 · Product code: **EBI** · Dental
Source: https://www.510kdatabase.net/k102654/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Sep 14, 2010
Decision date	Dec 3, 2010
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vertex-Dental B.V.**
Location	Claremont, NH, US
Contact	WILLIAM GREENROSE
510(k) history	8 submissions · 8 cleared · 2010-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k102654/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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