FDA 510(k) Premarket Notification

K203760 Tokuyama Universal Bond II

CLEARED

May 25, 2021
153 days to decision

K203760 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k203760/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Dec 23, 2020
Decision date	May 25, 2021
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tokuyama Dental Corporation**
Location	Washington, DC, US
Contact	Keith A. Barritt
510(k) history	19 submissions · 19 cleared · 2003-2021

REGULATORY CONSULTANT

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

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k203760/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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