FDA 510(k) Premarket Notification

K213401 DIAPLUS Universal

CLEARED

Jan 31, 2022
105 days to decision

K213401 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k213401/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Oct 18, 2021
Decision date	Jan 31, 2022
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**DiaDent Group International**
Location	Chungcheong Buk-Do, KR
Contact	Kab Sun Lee
510(k) history	19 submissions · 19 cleared · 2013-2026