

**K192273 DIAETCH Economic Package Type A, DIATECH
Regular Package, DIAETCH Refill Package Type A, DIAETCH
Intro Kit**

Feb 7, 2020
169 days to decision

K192273 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k192273/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Aug 22, 2019
Decision date	Feb 7, 2020
Days to decision	169 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k192273/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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