

K213339 DENU Composite Resin, DENU Flow ResinSep 23, 2022
351 days to decisionK213339 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k213339/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Oct 7, 2021
Decision date	Sep 23, 2022
Days to decision	351 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hdi, Inc.
Location	Seongnam-Si, KR
Contact	Taekyou Kim
510(k) history	2 submissions · 2 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213339/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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