

K210884 1Derful HS, 1Derful HTJul 27, 2021
124 days to decisionK210884 · Product code: **EIH** · Dental
Source: <https://www.510kdatabase.net/k210884/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Mar 25, 2021
Decision date	Jul 27, 2021
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	1derful, Inc.
Location	Brookshire, TX, US
Contact	Mohamad Alkassab
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Rac Dental Technologies
Contact	Robin Carden

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

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