

K193055 Purzir Dental ZirconiaMay 13, 2020
194 days to decisionK193055 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k193055/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Nov 1, 2019
Decision date	May 13, 2020
Days to decision	194 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3DBiocard
Location	Renton, WA, US
Contact	Gyu D. Cho
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Stuart R. Goldman

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

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