

K240419 UltraThineer Zirconia Slurry (5Y-B)Apr 12, 2024
59 days to decisionK240419 · Product code: **EIH** · Dental
Source: <https://www.510kdatabase.net/k240419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Feb 13, 2024
Decision date	Apr 12, 2024
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Micro Fabrication
Location	Maynard, MA, US
Contact	John Kawola
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Alvamed
Contact	Eric Bannon

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

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