

K242458 ArgenZ MTZOct 24, 2024
66 days to decisionK242458 · Product code: **EIH** · Dental
Source: <https://www.510kdatabase.net/k242458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Aug 19, 2024
Decision date	Oct 24, 2024
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Argen Corporation
Location	San Diego, CA, US
Contact	Paul Cascone
510(k) history	5 submissions · 5 cleared · 2016-2024

REGULATORY CONSULTANT

Consulting firm	Trisler Consulting (Db)
Contact	Patsy Trisler

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

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