

K220771 Stratasys TrueDentJul 7, 2022
113 days to decisionK220771 · Product code: **EBI** · Dental
Source: <https://www.510kdatabase.net/k220771/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Mar 16, 2022
Decision date	Jul 7, 2022
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stratasys, Ltd.
Location	Rehovot, IL
Contact	Melanie Glennon
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Melissa Burbage

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

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