

K253317 Cytrans™ Elashield

Jul 6, 2026
279 days to decision

K253317 · Product code: **LYC** · Dental
Source: <https://www.510kdatabase.net/k253317/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Sep 30, 2025
Decision date	Jul 6, 2026
Days to decision	279 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GC America, Inc.
Location	Alsip, IL, US
Contact	Futoshi Fusejima
510(k) history	128 submissions · 128 cleared · 1993-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k253317/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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