

K200767 SilverStream GelOct 8, 2020
197 days to decisionK200767 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200767/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Mar 25, 2020
Decision date	Oct 8, 2020
Days to decision	197 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Enzysurge , Ltd.
Location	Somerset, MA, US
Contact	Moshe Landsberg
510(k) history	3 submissions · 3 cleared · 2006-2020

REGULATORY CONSULTANT

Consulting firm	Bioreg Services
Contact	Daniel Albahari

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200767/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 22, 2026