

K220286 ELECTROCYN somaDec 21, 2022
323 days to decisionK220286 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220286/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Feb 1, 2022
Decision date	Dec 21, 2022
Days to decision	323 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	V3Bio Sdn. Bhd
Location	Simpang Ampat, MY
Contact	Shudipta Choudhury
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Xfda
Contact	Miriam Walls

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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