

K201138 AMSure® Single Use Saline Topical SolutionApr 14, 2021
351 days to decisionK201138 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Apr 28, 2020
Decision date	Apr 14, 2021
Days to decision	351 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Amsino Medical, Inc.
Location	Aurora, IL, US
Contact	Torsten Nilson
510(k) history	1 submissions · 1 cleared · 2021-2021

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