

K181423 AMSure Sterile Water, and Sterile Normal Saline for Wound FlushSep 7, 2018
99 days to decisionK181423 · Product code: **FRO** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k181423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	May 31, 2018
Decision date	Sep 7, 2018
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Amsino International, Inc.
Location	Ontario, CA, US
Contact	Jane Gao
510(k) history	27 submissions · 27 cleared · 2002-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181423/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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