

K240552 Irrisept Antimicrobial Wound LavageJun 18, 2024
111 days to decisionK240552 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k240552/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Feb 28, 2024
Decision date	Jun 18, 2024
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Irrimax Corporation
Location	Alpharetta, GA, US
Contact	Tanya Eberle
510(k) history	5 submissions · 5 cleared · 2009-2024

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