FDA 510(k) Premarket Notification

K242758 Atrauman® Ag

CLEARED

Dec 9, 2024
88 days to decision

K242758 · Product code: **FRO** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k242758/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Sep 12, 2024
Decision date	Dec 9, 2024
Days to decision	88 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hartmann USA, Inc.**
Location	Rock Hill, SC, US
Contact	Xiong Lee
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Qserve Group US**
Contact	Lorry Weaver

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov