

K243576 RENASYS Foam Wound Dressing Kit with AIRLOCK Technology and Soft PortFeb 18, 2025
91 days to decisionK243576 · Product code: **OMP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k243576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Nov 19, 2024
Decision date	Feb 18, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	RENASYS Gauze Wound Dressing Kit with AIRLOCK Technology and Soft Port

APPLICANT

Company	Smith & Nephew Medical, Ltd.
Location	Hull, GB
Contact	Ruby Uttley
510(k) history	7 submissions · 7 cleared · 2016-2025

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