

K231939 Renasys EdgeMay 24, 2024
329 days to decisionK231939 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231939/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Jun 30, 2023
Decision date	May 24, 2024
Days to decision	329 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231939/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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