

K260646 RENASYS EDGE (66803126)May 27, 2026
89 days to decisionK260646 · Product code: **OMP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k260646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Feb 27, 2026
Decision date	May 27, 2026
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew Medical, Ltd.
Location	Hull, GB
Contact	Chelsea Baker
510(k) history	8 submissions · 8 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260646/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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