

K223041 Renasys Edge (66803126)Nov 22, 2022
54 days to decisionK223041 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223041/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Sep 29, 2022
Decision date	Nov 22, 2022
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew Medical Limited
Location	Hull, GB
Contact	Zoe Smith
510(k) history	20 submissions · 20 cleared · 2016-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223041/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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