

K254019 Wound Geni NPWT SystemMay 4, 2026
140 days to decisionK254019 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k254019/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Dec 15, 2025
Decision date	May 4, 2026
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bechtel Medical, Inc.
Location	Collegeville, PA, US
Contact	John Gvoda
510(k) history	1 submissions · 1 cleared · 2026-2026

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