

**K243187 Nisus ONE Negative Pressure Wound Therapy System (OCMPP-100)**

Jun 27, 2025  
270 days to decision

K243187 · Product code: **OMP** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k243187/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Sep 30, 2024
Decision date	Jun 27, 2025
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cork Medical</b>
Location	Indianapolis, IN, US
Contact	Antonio Williams
510(k) history	3 submissions · 3 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k243187/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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