

**K212359 PWD Negative Pressure Wound Therapy System**Sep 21, 2022  
419 days to decisionK212359 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212359/>**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	Jul 29, 2021
Decision date	Sep 21, 2022
Days to decision	419 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Applied Tissue Technologies, LLC</b>
Location	Hingham, MA, US
Contact	Michael Broomhead
510(k) history	3 submissions · 3 cleared · 2019-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Lakeshore Medical Device Consulting</b>
Contact	Michael Lucey

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212359/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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