

K232379 PREVENT KitFeb 5, 2024
181 days to decisionK232379 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k232379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Aug 8, 2023
Decision date	Feb 5, 2024
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Clear Choice Therapeutics
Location	Raleigh, NC, US
Contact	Bret Batchelder
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Biotechnology Transfer, LLC
Contact	Cynthia Pritchard

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232379/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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