

K211277 Theia NPWT Foam Wound Dressing KitDec 16, 2021
233 days to decisionK211277 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211277/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Apr 27, 2021
Decision date	Dec 16, 2021
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Clear Choice Therapeutics, Inc.
Location	Athens, GA, US
Contact	Bret Batchelder
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	DuVal & Associates, P.A.
Contact	Kathy Herzog

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/k211277/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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