

K231646 Carilex VT¿200-i NXApr 17, 2024
317 days to decisionK231646 · Product code: **OMP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k231646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Jun 5, 2023
Decision date	Apr 17, 2024
Days to decision	317 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carilex Medical, Inc.
Location	Taoyuan City, TW
Contact	Pauline Su
510(k) history	4 submissions · 4 cleared · 2016-2024

REGULATORY CONSULTANT

Consulting firm	Mdi Consultants, Inc.
Contact	Aristotle Nafpliotis

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

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