

K161410 VT-One, VT-One 60daysOct 13, 2016
146 days to decisionK161410 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	May 20, 2016
Decision date	Oct 13, 2016
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161410/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026