

K042134 VERSATILE 1 WOUND VACUUM SYSTEMNov 1, 2004
84 days to decisionK042134 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k042134/>**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 | Aug 9, 2004 |
| Decision date | Nov 1, 2004 |
| Days to decision | 84 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Blue Sky Medical Group Incorporated |
| Location | Vista, CA, US |
| Contact | RICHARD WESTON |
| 510(k) history | 4 submissions · 4 cleared · 2004-2007 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042134/> 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 June 29, 2026