

K161599 UNO Negative Pressure Wound Therapy SystemApr 6, 2017
301 days to decisionK161599 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161599/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Negative Pressure Wound Therapy Powered Suction Pump (OMP) |
| Date received | Jun 9, 2016 |
| Decision date | Apr 6, 2017 |
| Days to decision | 301 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Genadyne Biotechnologies, Inc. |
| Location | Hicksville, NY, US |
| Contact | Chien Ming GOH |
| Website | https://www.genadyne.com |
| 510(k) history | 19 submissions · 19 cleared · 2008-2026 |

Genadyne Biotechnologies, Inc. specializes in advanced wound care solutions, particularly General & Plastic Surgery devices. Headquartered on Long Island, New York, the company manufactures and assembles products in the U.S. with a registered facility in Hicksville. Genadyne focuses on Negative Pressure Wound Therapy (NPWT) systems and advanced wound dressings, distributing globally across over 50 countries. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2008. General & Plastic Surgery devices represent 79% of its regula...
