

K221891 UNO Negative Pressure Wound Therapy SystemDec 14, 2022
168 days to decisionK221891 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221891/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Negative Pressure Wound Therapy Powered Suction Pump (OMP) |
| Date received | Jun 29, 2022 |
| Decision date | Dec 14, 2022 |
| Days to decision | 168 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Genadyne Biotechnologies, Inc. |
| Location | Hicksville, NY, US |
| Contact | Andrew 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...
