

**K190028 UNO 30**Jan 15, 2020  
373 days to decisionK190028 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190028/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Jan 7, 2019
Decision date	Jan 15, 2020
Days to decision	373 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Genadyne Biotechnologies</b>
Location	Hicksville, NY, US
Contact	Andrew Goh
510(k) history	2 submissions · 2 cleared · 2019-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190028/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026