

K180840 UNO Negative Pressure Wound Therapy SystemNov 30, 2018
245 days to decisionK180840 · Product code: **OMP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k180840/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Mar 30, 2018
Decision date	Nov 30, 2018
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	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...