

K221888 Genadyne Hybrid Foam DressingsJun 12, 2023
348 days to decisionK221888 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221888/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Jun 29, 2022
Decision date	Jun 12, 2023
Days to decision	348 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genadyne Biotechnologies, Inc.
Location	Hicksville, NY, US
Contact	Saiken Ho
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...