

K141961 GENADYNE SPIRO FOAM DRESSING KITMar 26, 2015
251 days to decisionK141961 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k141961/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Jul 18, 2014
Decision date	Mar 26, 2015
Days to decision	251 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...
