

K253429 Genadyne ASTRA NPWTMar 12, 2026
162 days to decisionK253429 · Product code: **OMP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253429/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Oct 1, 2025
Decision date	Mar 12, 2026
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	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...