

K143726 XLR8 PLUS (XLR8+)Jun 19, 2015
172 days to decisionK143726 · Product code: **OMP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k143726/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Dec 29, 2014
Decision date	Jun 19, 2015
Days to decision	172 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...
