

**K143574 Melodi Prime Breast Pump**Apr 21, 2015  
125 days to decisionK143574 · Product code: **HGX** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k143574/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Breast, Powered (HGX)
Date received	Dec 17, 2014
Decision date	Apr 21, 2015
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genadyne Biotechnologies, Inc.</b>
Location	Hicksville, NY, US
Contact	Chien Ming GOH
Website	<a href="https://www.genadyne.com">https://www.genadyne.com</a>
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...

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