

K223388 Invia® Integrated DressingJul 7, 2023
242 days to decisionK223388 · Product code: **OMP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k223388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Nov 7, 2022
Decision date	Jul 7, 2023
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medela AG
Location	Ch-6340 Baar, CH
Contact	Judith Bernardo
510(k) history	30 submissions · 30 cleared · 2002-2025

REGULATORY CONSULTANT

Consulting firm	Hyman, Phelps, & Mcnamara
Contact	Adrienne Lenz

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223388/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026