

K214112 Invia Ease Negative Pressure Wound Therapy (NPWT) System

Jul 26, 2022
208 days to decisionK214112 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k214112/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Dec 30, 2021
Decision date	Jul 26, 2022
Days to decision	208 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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