FDA 510(k) Premarket Notification

K232788 INSPIRA ART100

CLEARED

May 24, 2024
256 days to decision

K232788 · Product code: **DWA** · Cardiovascular
Source: https://www.510kdatabase.net/k232788/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Sep 11, 2023
Decision date	May 24, 2024
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inspira Technologies Oxy B.H.N. , Ltd.**
Location	Ra?Anana, IL
Contact	Dganit Litinsky
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**MCRA**
Contact	Fernando Aguel

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