FDA 510(k) Premarket Notification

K230530 SOZO Pro

CLEARED

May 4, 2023
66 days to decision

K230530 · Product code: **OBH** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k230530/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Extracellular Fluid, Lymphedema, Extremity (OBH)
Date received	Feb 27, 2023
Decision date	May 4, 2023
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**ImpediMed Limited**
Location	San Diego, CA, US
Contact	Dennis Schlaht
510(k) history	12 submissions · 12 cleared · 2011-2026

REGULATORY CONSULTANT

Consulting firm	**Impedimed, Inc.**
Contact	Richard Hines

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