FDA 510(k) Premarket Notification

K203473 SOZO

CLEARED

Apr 19, 2021
145 days to decision

K203473 · Product code: **DSB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k203473/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plethysmograph, Impedance (DSB)
Date received	Nov 25, 2020
Decision date	Apr 19, 2021
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Impedimed, Inc.**
Contact	Reuben Lawson

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