

**K232089 SOZO Pro**Oct 17, 2023  
96 days to decisionK232089 · Product code: **DSB** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k232089/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plethysmograph, Impedance (DSB)
Date received	Jul 13, 2023
Decision date	Oct 17, 2023
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Imedimed, Inc.</b>
Contact	Richard Hines

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

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