

**K253224 MySOZO Software version 6.0.1.2 (SW version 6.0.1.2)**Jan 28, 2026  
121 days to decisionK253224 · Product code: **OBH** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k253224/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Extracellular Fluid, Lymphedema, Extremity (OBH)
Date received	Sep 29, 2025
Decision date	Jan 28, 2026
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253224/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026