

**K100811 IMPEDIMED - EXTRACELLULAR FLUID ANALYZER
MODEL: L-DEX U400**Nov 4, 2011
592 days to decisionK100811 · Product code: **OBH** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k100811/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Extracellular Fluid, Lymphedema, Extremity (OBH)
Date received	Mar 22, 2010
Decision date	Nov 4, 2011
Days to decision	592 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100811/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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