

**K080825 IMPEDIMED EXTRA CELLULAR FLUID ANALYSIS,
MODEL L-DEX U400**Oct 3, 2008
193 days to decisionK080825 · Product code: **OBH** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k080825/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Monitor, Extracellular Fluid, Lymphedema, Extremity (OBH)
Date received	Mar 24, 2008
Decision date	Oct 3, 2008
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Impedimed Pty , Ltd.
Location	Brisbane, Queensland, AU
Contact	PHILIP S AUCKLAND
510(k) history	4 submissions · 2 cleared · 2005-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080825/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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