

**K130338 IMPEDIMED - BIS EXTRA CELLULAR FLUID
ANALYSIS**May 31, 2013
109 days to decisionK130338 · Product code: **OBH** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k130338/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Extracellular Fluid, Lymphedema, Extremity (OBH)
Date received	Feb 11, 2013
Decision date	May 31, 2013
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	ImpediMed Limited
Location	San Diego, CA, US
Contact	John j Smith, M.D., J.D.
510(k) history	12 submissions · 12 cleared · 2011-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130338/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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