

K050415 IMPEDIMED-EXTRACELLULAR FLUID ANALYSISMar 30, 2007
770 days to decisionK050415 · Product code: **OBH** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k050415/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Monitor, Extracellular Fluid, Lymphedema, Extremity (OBH)
Date received	Feb 18, 2005
Decision date	Mar 30, 2007
Days to decision	770 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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