FDA 510(k) Premarket Notification

K130338 IMPEDIMED - BIS EXTRA CELLULAR FLUID ANALYSIS

CLEARED

May 31, 2013
109 days to decision

K130338 · 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