FDA 510(k) Premarket Notification

CLEARED

K100811 IMPEDIMED - EXTRACELLULAR FLUID ANALYZER MODEL: L-DEX U400

Nov 4, 2011
592 days to decision

K100811 · 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