FDA 510(k) Premarket Notification

K180126 SOZO

CLEARED

Apr 16, 2018
90 days to decision

K180126 · Product code: **OBH** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k180126/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Extracellular Fluid, Lymphedema, Extremity (OBH)
Date received	Jan 16, 2018
Decision date	Apr 16, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**ImpediMed Limited**
Location	San Diego, CA, US
Contact	Catherine Kingsford
510(k) history	12 submissions · 12 cleared · 2011-2026