FDA 510(k) Premarket Notification

K063142 MANUAL PD-IO

CLEARED

Dec 8, 2006
53 days to decision

K063142 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k063142/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Oct 16, 2006
Decision date	Dec 8, 2006
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary
Other names	POWERED PD-IO

APPLICANT

Company	**Vidacare Corporation**
Location	Irvine, CA, US
Contact	GRACE HOLLAND
510(k) history	19 submissions · 19 cleared · 2004-2014