FDA 510(k) Premarket Notification

K101026 POWERED PD-IO INFUSION SYSTEM, EZ-IO HUMERAL HEAD, POWERED PH-IO

CLEARED

Jul 27, 2010
105 days to decision

K101026 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k101026/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Apr 13, 2010
Decision date	Jul 27, 2010
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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