FDA 510(k) Premarket Notification

K062422 HUMERAL HEAD, MANUAL DRIVER

CLEARED

Nov 7, 2006
81 days to decision

K062422 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k062422/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 18, 2006
Decision date	Nov 7, 2006
Days to decision	81 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