FDA 510(k) Premarket Notification

K062331 HIGHPAK-12

CLEARED

Jul 10, 2007
334 days to decision

K062331 · Product code: **MPD** · Cardiovascular
Source: https://www.510kdatabase.net/k062331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Auxiliary Power Supply (ac Or Dc) For Low-energy Dc-defibrillator (MPD)
Date received	Aug 10, 2006
Decision date	Jul 10, 2007
Days to decision	334 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ad Elektronik GmbH**
Location	Tunersville, NJ, US
Contact	GREGORY J MATHISON
510(k) history	2 submissions · 2 cleared · 2003-2007