FDA 510(k) Premarket Notification

K083765 MAXGUARD ADVANCED LUER ACTIVATED DEVICE WITH ANTIMICROBIAL

CLEARED

Dec 30, 2008
12 days to decision

K083765 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k083765/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Dec 18, 2008
Decision date	Dec 30, 2008
Days to decision	12 days
Third-party review	Yes
Summary / Statement	Statement

APPLICANT

Company	**Medegen Medical Manufacturing Services**
Location	Trabuco Canyon, CA, US
Contact	MATTHEW FRIED
510(k) history	4 submissions · 4 cleared · 2005-2008