FDA 510(k) Premarket Notification

K080665 NOVOLET

CLEARED

May 13, 2008
64 days to decision

K080665 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k080665/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Mar 10, 2008
Decision date	May 13, 2008
Days to decision	64 days
Third-party review	Yes
Summary / Statement	Statement

APPLICANT

Company	**U.S. Safety Syringes Co., Inc.**
Location	Fort Lauderdale, FL, US
Contact	CHRISTINA SMITH
510(k) history	7 submissions · 7 cleared · 2000-2009