FDA 510(k) Premarket Notification

K071998 ARROW ECHOGENIC INTRODUCER NEEDLE COMPONENT

CLEARED

Sep 26, 2007
65 days to decision

K071998 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k071998/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jul 23, 2007
Decision date	Sep 26, 2007
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Arrow Intl., Inc.**
Location	Mchenry, IL, US
Contact	KIRSTEN STOWELL
510(k) history	110 submissions · 105 cleared · 1976-2010