FDA 510(k) Premarket Notification

K071567 AUTOSAFE-REFLEX SAFETY NEEDLE, AUTOSAFE ADVANTAGE SAFETY NEEDLE

CLEARED

Sep 14, 2007
99 days to decision

K071567 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k071567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 7, 2007
Decision date	Sep 14, 2007
Days to decision	99 days
Third-party review	Yes
Summary / Statement	Statement

APPLICANT

Company	**Autosafe-Refelx, Inc.**
Location	Alpharetta, GA, US
Contact	JOHN D STEPHENS
510(k) history	1 submissions · 1 cleared · 2007-2007