FDA 510(k) Premarket Notification

K051783 ARTSANA PEN NEEDLES, ARTSANA INJECTION NEEDLES

CLEARED

Oct 4, 2005
95 days to decision

K051783 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k051783/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jul 1, 2005
Decision date	Oct 4, 2005
Days to decision	95 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Artsana S.P.A**
Location	Bristol, WI, US
Contact	LARA N SIMMONS
510(k) history	3 submissions · 3 cleared · 2005-2016