FDA 510(k) Premarket Notification

K113469 NIPRO HUBER INFUSION, EXCEL HUBER NEEDLE

CLEARED

Oct 18, 2012
331 days to decision

K113469 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k113469/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 22, 2011
Decision date	Oct 18, 2012
Days to decision	331 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nipro Medical Corporation**
Location	Lexington, KY, US
Contact	JESSICA OSWALD
510(k) history	34 submissions · 34 cleared · 2005-2026