

**K113469 NIPRO HUBER INFUSION, EXCEL HUBER NEEDLE**Oct 18, 2012  
331 days to decisionK113469 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k113469/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113469/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 13, 2026