

**K120261 PPS PI PRESSURE INJECTABLE SAFETY HUBER  
NEEDLE WITHOUT LATERAL INJECTION SITE, PPS PI  
PRESSURE INJECTABLE SAFETY HUBER**May 2, 2012  
96 days to decisionK120261 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k120261/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jan 27, 2012
Decision date	May 2, 2012
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Perouse Medical</b>
Location	France, FR
Contact	Isabelle Jeanty
510(k) history	3 submissions · 3 cleared · 2012-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120261/> 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 7, 2026