

**K991623 NIPRO ARTERIAL VENOUS FISTULA NEEDLE,  
AGULHA PARA FISTULA ARTERIO-VENOSA, AGUJA PARA  
FISTULA ARTERIO VENOSA**Aug 9, 1999  
90 days to decisionK991623 · Product code: FIE · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k991623/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	May 11, 1999
Decision date	Aug 9, 1999
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Nipro Medical Corp.</b>
Location	Miami, FL, US
Contact	KAELYN HADLEY
510(k) history	27 submissions · 27 cleared · 1997-2010

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991623/> Data sourced from FDA 510(k) public records (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. - Generated June 21, 2026