FDA 510(k) Premarket Notification

CLEARED

K991623 NIPRO ARTERIAL VENOUS FISTULA NEEDLE, AGULHA PARA FISTULA ARTERIO-VENOSA, AGUJA PARA FISTULA ARTERIO VENOSA

Aug 9, 1999
90 days to decision

K991623 · 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	**Nipro Medical Corp.**
Location	Miami, FL, US
Contact	KAELYN HADLEY
510(k) history	27 submissions · 27 cleared · 1997-2010