FDA 510(k) Premarket Notification

K100520 NIPRO BIOHOLE NEEDLE WITH CAPICK SCAB REMOVER

CLEARED

Mar 17, 2010
22 days to decision

K100520 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k100520/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Fistula (FIE)
Date received	Feb 23, 2010
Decision date	Mar 17, 2010
Days to decision	22 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