FDA 510(k) Premarket Notification

K063368 NIPRO BIOHOLE NEEDLE

CLEARED

Feb 5, 2007
90 days to decision

K063368 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k063368/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Nov 7, 2006
Decision date	Feb 5, 2007
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nipro Medical Corp.**
Location	Miami, FL, US
Contact	JESSICA OSWALD
510(k) history	27 submissions · 27 cleared · 1997-2010