

K150084 Argyle; Polyvinyl Chloride (PVC) and Kangaroo; Polyurethane (PU) Neonatal and Pediatric Feeding Tubes with ENFit connector

Jul 13, 2015
179 days to decision

K150084 · Product code: PIF · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k150084/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Tubes With Enteral Specific Connectors (PIF)
Date received	Jan 15, 2015
Decision date	Jul 13, 2015
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien
Location	North Haven, CT, US
Contact	SONA MANICKAM
510(k) history	130 submissions · 126 cleared · 2008-2024

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...