FDA 510(k) Premarket Notification

CLEARED

K132567 ARGYLE PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN, ARGYLE PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN

Nov 5, 2013
82 days to decision

K132567 · Product code: **LJS** · General Hospital
Source: https://www.510kdatabase.net/k132567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Aug 15, 2013
Decision date	Nov 5, 2013
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Covidien**
Location	North Haven, CT, US
Contact	DOLLY MISTRY
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...