FDA 510(k) Premarket Notification

K130904 TRELLIS-8 PERIPHERAL INFUSION SYSTEM

CLEARED

Oct 25, 2013
207 days to decision

K130904 · Product code: **QEY** · Cardiovascular
Source: https://www.510kdatabase.net/k130904/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Apr 1, 2013
Decision date	Oct 25, 2013
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Covidien**
Location	North Haven, CT, US
Contact	JENNIFER SULLIVAN
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...