FDA 510(k) Premarket Notification

K042461 KENDALL ARGYLE 2 FR DOUBLE LUMEN NEONATAL/PEDIATRIC PICC, MODEL 43304

CLEARED

Dec 10, 2004
91 days to decision

K042461 · Product code: **LJS** · General Hospital
Source: https://www.510kdatabase.net/k042461/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Sep 10, 2004
Decision date	Dec 10, 2004
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kendall**
Location	Mansfield, MA, US
Contact	PAUL W EVANS
510(k) history	12 submissions · 10 cleared · 2004-2009