FDA 510(k) Premarket Notification

CLEARED

K143102 Multi-Lumen Acute Hemodialysis Catheter for High Volume Infusions

Jul 24, 2015
268 days to decision

K143102 · Product code: **NIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k143102/

SUBMISSION DETAILS

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Triple Lumen, Non-implanted (NIE)
Date received	Oct 29, 2014
Decision date	Jul 24, 2015
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Arrow International, Inc. (Subsidiary of Teleflex, Inc.)**
Location	Reading, PA, US
Contact	Debra Grodt
510(k) history	8 submissions · 7 cleared · 2015-2018