FDA 510(k) Premarket Notification

K220363 VPS Rhythm DLX Device with TipTracker Technology

CLEARED

Aug 22, 2022
195 days to decision

K220363 · Product code: **LJS** · General Hospital
Source: https://www.510kdatabase.net/k220363/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Feb 8, 2022
Decision date	Aug 22, 2022
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Arrow International, LLC (A subsidiary of Teleflex, Inc.)**
Location	Morrisville, NC, US
Contact	Elizabeth Duncan
510(k) history	4 submissions · 4 cleared · 2022-2025