FDA 510(k) Premarket Notification

CLEARED

K162181 Protek Duo Venous Dilator Set, Protek Solo Venous Dilator Set

Jan 6, 2017
155 days to decision

K162181 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k162181/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Aug 4, 2016
Decision date	Jan 6, 2017
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiacassist, Inc.**
Location	Pittsburgh, PA, US
Contact	GREG JOHNSON
510(k) history	21 submissions · 21 cleared · 2000-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k162181/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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