FDA 510(k) Premarket Notification

K172487 Coaxial Dilator Set (Micro-Introducer)

CLEARED

Oct 16, 2017
60 days to decision

K172487 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k172487/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Aug 17, 2017
Decision date	Oct 16, 2017
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Galt Medical Corp.**
Location	Garland, TX, US
Contact	David Derrick
510(k) history	14 submissions · 12 cleared · 1999-2019