

K172487 Coaxial Dilator Set (Micro-Introducer)Oct 16, 2017
60 days to decisionK172487 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172487/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 21, 2026