

K162389 Medcomp Vessel DilatorJun 1, 2017
279 days to decisionK162389 · Product code: **DRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k162389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Aug 26, 2016
Decision date	Jun 1, 2017
Days to decision	279 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medcomp (Medical Components)
Location	Harleysville, PA, US
Contact	COURTNEY NIX
510(k) history	7 submissions · 7 cleared · 2009-2017

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