

**K182914 MC3 Vascular Access Kit 21030**Oct 29, 2018  
11 days to decisionK182914 · Product code: **DRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k182914/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Oct 18, 2018
Decision date	Oct 29, 2018
Days to decision	11 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mc3 Incorporated</b>
Location	Dexter, MI, US
Contact	Adam Viitala
510(k) history	4 submissions · 4 cleared · 2017-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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