FDA 510(k) Premarket Notification

CLEARED

K182914 MC3 Vascular Access Kit 21030

Oct 29, 2018
11 days to decision

K182914 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k182914/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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