K192283 MEDRON Vessel Dilator - 6F x 22cm HDPE Dilator, MEDRON Vessel Dilator - 15.5F - 17.5F HDPE Dilator

CLEARED

May 6, 2020
258 days to decision

K192283 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k192283/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Aug 22, 2019
Decision date	May 6, 2020
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medron, LLC**
Location	Salt Lake City, UT, US
Contact	David Kujawa
510(k) history	1 submissions · 1 cleared · 2020-2020