

**K192283 MEDRON Vessel Dilator - 6F x 22cm HDPE Dilator,  
MEDRON Vessel Dilator - 15.5F - 17.5F HDPE Dilator**May 6, 2020  
258 days to decisionK192283 · Product code: **DRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k192283/>**SUBMISSION DETAILS**

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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**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192283/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026