

**K192195 Sterile Dilator**Sep 26, 2019  
44 days to decisionK192195 · Product code: **DRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k192195/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Aug 13, 2019
Decision date	Sep 26, 2019
Days to decision	44 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Galt Medical Corp.</b>
Location	Garland, TX, US
Contact	David Derrick
510(k) history	14 submissions · 12 cleared · 1999-2019

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192195/> 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 21, 2026