FDA 510(k) Premarket Notification

K192195 Sterile Dilator

CLEARED

Sep 26, 2019
44 days to decision

K192195 · 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	**Galt Medical Corp.**
Location	Garland, TX, US
Contact	David Derrick
510(k) history	14 submissions · 12 cleared · 1999-2019