FDA 510(k) Premarket Notification

K170488 Peak Left Ventricular Vent Cannula, 20 Fr.

CLEARED

Aug 10, 2017
174 days to decision

K170488 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k170488/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Feb 17, 2017
Decision date	Aug 10, 2017
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary
Other names	Peak Left Ventricular Vent Cannula, 18 Fr; Peak Left Ventricular Vent Cannula, 16 Fr

APPLICANT

Company	**Surge Cardiovascular**
Location	Grand Rapids, MI, US
Contact	Rick Shorey
510(k) history	1 submissions · 1 cleared · 2017-2017