FDA 510(k) Premarket Notification

K152864 Merge Hemo

CLEARED

Apr 7, 2016
190 days to decision

K152864 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k152864/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Sep 30, 2015
Decision date	Apr 7, 2016
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Merge Healthcare Incorporated**
Location	Hartland, WI, US
Contact	MIKE DIEDRICK
510(k) history	8 submissions · 8 cleared · 2016-2025