FDA 510(k) Premarket Notification

K191502 Heraeus Peripheral Guidewire

CLEARED

Nov 26, 2019
173 days to decision

K191502 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k191502/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jun 6, 2019
Decision date	Nov 26, 2019
Days to decision	173 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Heraeus Medical Components, LLC**
Location	Plymouth, MN, US
Contact	Chelsea Pioske
510(k) history	4 submissions · 4 cleared · 2017-2019