FDA 510(k) Premarket Notification

K181372 Argos

CLEARED

Dec 13, 2018
204 days to decision

K181372 · Product code: **DXG** · Cardiovascular
Source: https://www.510kdatabase.net/k181372/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	May 23, 2018
Decision date	Dec 13, 2018
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Retia Medical, LLC**
Location	Valhalla, NY, US
Contact	Marc Zemel
510(k) history	1 submissions · 1 cleared · 2018-2018