FDA 510(k) Premarket Notification

CLEARED

K172457 Deltex Medical CardioQ-EDM+, Deltex Medical CardioQ-EDM

Jun 28, 2018
318 days to decision

K172457 · Product code: **DPW** · Cardiovascular
Source: https://www.510kdatabase.net/k172457/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	Aug 14, 2017
Decision date	Jun 28, 2018
Days to decision	318 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Deltex Medical Limited**
Location	Stevenage, Hertfordshire, GB
Contact	Mark Baylis
510(k) history	6 submissions · 6 cleared · 2009-2018