FDA 510(k) Premarket Notification

K171410 ePatch

CLEARED

Jan 4, 2018
234 days to decision

K171410 · Product code: **DSH** · Cardiovascular
Source: https://www.510kdatabase.net/k171410/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	May 15, 2017
Decision date	Jan 4, 2018
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Braemar Manufacturing, LLC**
Location	San Diego, CA, US
Contact	Kent Sayler
510(k) history	3 submissions · 3 cleared · 2013-2018