

K170831 EpiAccess SystemMay 9, 2017
50 days to decisionK170831 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k170831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Mar 20, 2017
Decision date	May 9, 2017
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Epiep, Inc.
Location	New Haven, CT, US
Contact	Pamela Bunes
510(k) history	2 submissions · 2 cleared · 2014-2017

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