

K153494 HQS Introducer (Model 2064-HQS)Aug 25, 2016
265 days to decisionK153494 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k153494/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 4, 2015
Decision date	Aug 25, 2016
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alseal
Location	Besancon, FR
Contact	Jean-Francois M Delforge
510(k) history	3 submissions · 3 cleared · 2012-2016

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