

K142829 Flexor Tuohy-Borst Side-Arm Introducer, Ansel ModificationJul 28, 2015
301 days to decisionK142829 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k142829/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 30, 2014
Decision date	Jul 28, 2015
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary
Other names	Flexor Check-Flo Introducer, Ansel Modification; Flexor Check-Flo Introducers, Ansel Modification with High-Flex Dilator and Hydrophilic Coating; Flexor Check-Flo Introducer Balkin Up and Over Contralateral Design; Flexor Up and Over Balkin Contralateral Introducer; Flexor Check-Flo Introducer, Raabe Modification; Flexor Check-Flo Performer Introducer

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Sarah Reeves
510(k) history	175 submissions · 153 cleared · 2006-2024

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