

K170431 CT Syringe for Stellant Injectors (with & without Spikes, Prime Tubes, & Fill Tubes), CT Syringe Dual Pack for Stellant Injectors (with & without Spikes, Prime Tubes, & Fill Tubes), Single Fascia and Ram Tip, Dual Fascia and Ram TipAug 18, 2017
186 days to decisionK170431 · Product code: DXT · Cardiovascular
Source: <https://www.510kdatabase.net/k170431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Feb 13, 2017
Decision date	Aug 18, 2017
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coeur, Inc.
Location	Lebanon, TN, US
Contact	Priscilla Cliner
510(k) history	14 submissions · 14 cleared · 2005-2017

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