

K152789 FLEX SCORING CATHETERMay 25, 2016
243 days to decisionK152789 · Product code: **PNO** · Cardiovascular
Source: <https://www.510kdatabase.net/k152789/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Sep 25, 2015
Decision date	May 25, 2016
Days to decision	243 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Venturemed Group
Location	Sylvania, OH, US
Contact	TIFFINI DIAGE
510(k) history	1 submissions · 1 cleared · 2016-2016

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