

K190753 EverCross™ 0.035 OTW PTA Dilatation CatheterApr 23, 2019
29 days to decisionK190753 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k190753/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Mar 25, 2019
Decision date	Apr 23, 2019
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic, Inc. (Formerly D.B.A. Ev3, Inc. Covidien, LLC.)
Location	Plymouth, MN, US
Contact	Breanna Fautsch
510(k) history	1 submissions · 1 cleared · 2019-2019

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