

K192399 Infinity Angioplasty Balloon CatheterMay 20, 2020
260 days to decisionK192399 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k192399/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Sep 3, 2019
Decision date	May 20, 2020
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Infinity Angioplasty Balloon Company, LLC
Location	Toledo, OH, US
Contact	Tiffini Wittwer
510(k) history	1 submissions · 1 cleared · 2020-2020

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