

K211910 Z-6 Atrioseptostomy CatheterJul 19, 2021
28 days to decisionK211910 · Product code: **DXF** · CardiovascularSource: <https://www.510kdatabase.net/k211910/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Septostomy (DXF)
Date received	Jun 21, 2021
Decision date	Jul 19, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	NuMED, Inc.
Location	Hopkinton, NY, US
Contact	Nichelle LaFlesh
510(k) history	49 submissions · 47 cleared · 1985-2022

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