FDA 510(k) Premarket Notification

K001804 NUMED Z-5 ATRIOSEPTOSTOMY CATHETER

CLEARED

Jul 12, 2000
27 days to decision

K001804 · Product code: **DXF** · Cardiovascular
Source: https://www.510kdatabase.net/k001804/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Septostomy (DXF)
Date received	Jun 15, 2000
Decision date	Jul 12, 2000
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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