FDA 510(k) Premarket Notification

K931009 TYSHAK PERIPHERAL BALLOON DILATION CATHETER

CLEARED

Dec 21, 1993
305 days to decision

K931009 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k931009/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Feb 19, 1993
Decision date	Dec 21, 1993
Days to decision	305 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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