FDA 510(k) Premarket Notification

K912317 SCHNEIDER MONORAIL 421 PERCU TRANS ANGIO PTA CATH

CLEARED

Aug 22, 1991
90 days to decision

K912317 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k912317/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 24, 1991
Decision date	Aug 22, 1991
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Schneider Intl., Ltd.**
Location	Minneapolis, MN, US
Contact	ROBERT L ULLEN
510(k) history	22 submissions · 22 cleared · 1989-1995