

**K912317 SCHNEIDER MONORAIL 421 PERCU TRANS ANGIO
PTA CATH**Aug 22, 1991
90 days to decisionK912317 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912317/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 2, 2026