

K972800 PTA BALLOON CATHETERApr 16, 1998
262 days to decisionK972800 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k972800/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jul 28, 1997
Decision date	Apr 16, 1998
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook, Inc.
Location	Mchenry, IL, US
Contact	APRIL LAVENDER
510(k) history	190 submissions · 179 cleared · 1976-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972800/> 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 May 14, 2026