

K954638 5 FR PICC-LINE CATHETERApr 22, 1996
199 days to decisionK954638 · Product code: **LJS** · General Hospital
Source: <https://www.510kdatabase.net/k954638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Oct 6, 1995
Decision date	Apr 22, 1996
Days to decision	199 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Vygon Corp.
Location	East Rutherford, NJ, US
Contact	ANNE MARIE CESARIO
510(k) history	48 submissions · 46 cleared · 1985-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954638/> 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 26, 2026