

**K910486 8 FR SINGLE LUMEN HIGH PERFORMANCE
CATHETER**Apr 19, 1991
72 days to decisionK910486 · Product code: **LJS** · General Hospital
Source: <https://www.510kdatabase.net/k910486/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS) |
| Date received | Feb 6, 1991 |
| Decision date | Apr 19, 1991 |
| Days to decision | 72 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Davol, Inc. |
| Location | Mchenry, IL, US |
| Contact | JACK SPEER |
| 510(k) history | 50 submissions · 47 cleared · 1977-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k910486/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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