

K953436 STRATO/INFUSAID INFUSE-A-CATH SINGLE LUMEN SILICONE CENTRAL VENOUS CATHETER SYSTEMS

Oct 4, 1995
75 days to decision

K953436 · Product code: **LJS** · General Hospital
Source: <https://www.510kdatabase.net/k953436/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Jul 21, 1995
Decision date	Oct 4, 1995
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Strato/Infusaid, Inc.
Location	Norwood, MA, US
Contact	CRAIG M AUDET
510(k) history	11 submissions · 10 cleared · 1995-1996

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Device record: <https://www.510kdatabase.net/k953436/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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