

K884620 ASD SINGLE LUMEN NEEDLENov 21, 1988
17 days to decisionK884620 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k884620/>**SUBMISSION DETAILS**

| | |
|-----------------------|----------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received | Nov 4, 1988 |
| Decision date | Nov 21, 1988 |
| Days to decision | 17 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biosurge, Inc. |
| Location | Rochester, NY, US |
| Contact | LISA JOERGER |
| 510(k) history | 5 submissions · 5 cleared · 1987-1988 |

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