

K950560 SALINE SOLUTINE, STERILEMay 30, 1995
111 days to decisionK950560 · Product code: **IGE** · Pathology
Source: <https://www.510kdatabase.net/k950560/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Solution, Formalin Ammonium Bromide (IGE) |
| Date received | Feb 8, 1995 |
| Decision date | May 30, 1995 |
| Days to decision | 111 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Busse Hospital Disposables, Inc. |
| Location | Mchenry, IL, US |
| Contact | EILEEN RAMA |
| 510(k) history | 31 submissions · 29 cleared · 1983-2012 |

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