

K953325 SAS SHIGELLA BOYDII TYPE 4 ANTISERUMAug 2, 1995
20 days to decisionK953325 · Product code: **GNB** · Microbiology
Source: <https://www.510kdatabase.net/k953325/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antisera, All Types, Shigella Spp. (GNB) |
| Date received | Jul 13, 1995 |
| Decision date | Aug 2, 1995 |
| Days to decision | 20 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Sa Scientific, Inc. |
| Location | San Antonio, TX, US |
| Contact | HARBI SHADFAN |
| 510(k) history | 199 submissions · 199 cleared · 1993-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953325/> 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 June 21, 2026