

K953324 SAS SHIGELLA BOYDII TYPE 3 ANTISERUNAug 2, 1995
20 days to decisionK953324 · Product code: **GNB** · Microbiology
Source: <https://www.510kdatabase.net/k953324/>**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/k953324/> 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