

K013379 SAS STREPALERTDec 12, 2001
61 days to decisionK013379 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k013379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Oct 12, 2001
Decision date	Dec 12, 2001
Days to decision	61 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013379/> 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