

K801159 STREPTO-SEC TMJun 20, 1980
40 days to decisionK801159 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k801159/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	May 11, 1980
Decision date	Jun 20, 1980
Days to decision	40 days
Third-party review	No

APPLICANT

Company	Organon, Inc.
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1977-1995

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Device record: <https://www.510kdatabase.net/k801159/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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