

K861835 MICROTRAK NEISERRIA GONORRHOEAE CULTURE TESTMay 29, 1986
16 days to decisionK861835 · Product code: **GTH** · Microbiology
Source: <https://www.510kdatabase.net/k861835/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Fluorescent (direct Test), All Groups, N. Gonorrhoeae (GTH)
Date received	May 13, 1986
Decision date	May 29, 1986
Days to decision	16 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
Contact	ELEANOR V CHIU
510(k) history	448 submissions · 447 cleared · 1976-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k861835/> 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 28, 2026