

**K850739 AMENDMENT TO LABELING MICROTRAK HSV 1/HSV
2 DIRECT**Mar 11, 1985
24 days to decisionK850739 · Product code: **GQL** · Microbiology
Source: <https://www.510kdatabase.net/k850739/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Fluorescent, Herpesvirus Hominis 1,2 (GQL)
Date received	Feb 15, 1985
Decision date	Mar 11, 1985
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k850739/> 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