

K971101 HSV-2 ANTIGEN CONTROL SLIDESJul 1, 1997
97 days to decisionK971101 · Product code: **GQN** · Microbiology
Source: <https://www.510kdatabase.net/k971101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Herpesvirus Hominis 1,2 (GQN)
Date received	Mar 26, 1997
Decision date	Jul 1, 1997
Days to decision	97 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Viral Antigens, Inc.
Location	Memphis, TN, US
Contact	TERRY S RATCLIFFE
510(k) history	6 submissions · 6 cleared · 1990-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971101/> 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 29, 2026