

K853695 RESPIRATORY SYNCYTIAL VIRUS ID REAGENTDec 4, 1985
91 days to decisionK853695 · Product code: **GQG** · Microbiology
Source: <https://www.510kdatabase.net/k853695/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Controls), Respiratory Syncytial Virus (GQG)
Date received	Sep 4, 1985
Decision date	Dec 4, 1985
Days to decision	91 days
Third-party review	No

APPLICANT

Company	Viomed Laboratories, Inc.
Location	Mchenry, IL, US
Contact	BONITA BASKIN
510(k) history	25 submissions · 25 cleared · 1983-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853695/>; 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 May 14, 2026