FDA 510(k) Premarket Notification

# K853695 RESPIRATORY SYNCYTIAL VIRUS ID REAGENT

**CLEARED**

Dec 4, 1985
91 days to decision

K853695 · Product code: **GQG** · Microbiology
Source: https://www.510kdatabase.net/k853695/

## SUBMISSION DETAILS

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