

K971662 ELVIS HSV ID/TYPING TEST SYSTEMNov 18, 1997
203 days to decisionK971662 · Product code: **GQN** · Microbiology
Source: <https://www.510kdatabase.net/k971662/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antigen, Cf (including Cf Control), Herpesvirus Hominis 1,2 (GQN) |
| Date received | Apr 29, 1997 |
| Decision date | Nov 18, 1997 |
| Days to decision | 203 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Diagnostic Hybrids, Inc. |
| Location | Athens, OH, US |
| Contact | J.L. BROWN |
| 510(k) history | 37 submissions · 36 cleared · 1988-2014 |

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