

K880679 BION CMV-G TEST SYSTEM

Jun 3, 1988
105 days to decision

K880679 · Product code: **GQH** · Microbiology
Source: <https://www.510kdatabase.net/k880679/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antigen, Cf (including Cf Control), Cytomegalovirus (GQH) |
| Date received | Feb 19, 1988 |
| Decision date | Jun 3, 1988 |
| Days to decision | 105 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Bion Ent., Ltd. |
| Location | Mchenry, IL, US |
| Contact | EDWARD NOWAKOWSKI |
| 510(k) history | 14 submissions · 14 cleared · 1980-1993 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k880679/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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