

K885298 VISUWELL REAGIN TEST 960 TEST KITMar 15, 1989
78 days to decisionK885298 · Product code: **GMP** · Microbiology
Source: <https://www.510kdatabase.net/k885298/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antisera, Control For Nontreponemal Tests (GMP) |
| Date received | Dec 27, 1988 |
| Decision date | Mar 15, 1989 |
| Days to decision | 78 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Allelix Diagnostics, Inc. |
| Location | Canada L4v 1p1, CA |
| Contact | JANET SHAW |
| 510(k) history | 2 submissions · 2 cleared · 1988-1989 |

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