

K972986 ACCURUN 140 RUBELLA IGG POSITIVE CONTROLOct 8, 1997
58 days to decisionK972986 · Product code: **MJX** · Microbiology
Source: <https://www.510kdatabase.net/k972986/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Kit, Serological, Positive Control (MJX) |
| Date received | Aug 11, 1997 |
| Decision date | Oct 8, 1997 |
| Days to decision | 58 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Boston Biomedica, Inc. |
| Location | West Bridgewater, MA, US |
| Contact | PATRICIA E GARRETT |
| 510(k) history | 12 submissions · 12 cleared · 1997-2003 |

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