

K893755 RUBAGENAug 21, 1989
94 days to decisionK893755 · Product code: **LQN** · Microbiology
Source: <https://www.510kdatabase.net/k893755/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Agglutination Assay, Rubella (LQN) |
| Date received | May 19, 1989 |
| Decision date | Aug 21, 1989 |
| Days to decision | 94 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Biokit USA, Inc. |
| Location | Mchenry, IL, US |
| Contact | CASTELLS |
| 510(k) history | 16 submissions · 16 cleared · 1984-1993 |

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