

K972035 SPROX TEST STRIPSAug 29, 1997
88 days to decisionK972035 · Product code: **JOJ** · General Hospital
Source: <https://www.510kdatabase.net/k972035/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Indicator, Physical/chemical Sterilization Process (JOJ) |
| Date received | Jun 2, 1997 |
| Decision date | Aug 29, 1997 |
| Days to decision | 88 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Serim Research Corp. |
| Location | Elkhart, IN, US |
| Contact | ROBERT C BOGUSLASKI |
| Website | https://www.serim.com |
| 510(k) history | 27 submissions · 27 cleared · 1990-2012 |

Serim Research Corp. develops and manufactures diagnostic test strips based on proprietary dry reagent technology. The company operates a fully integrated research and development and manufacturing facility in Elkhart, Indiana. Since 1988, Serim has specialized in colorimetric chemistries, reagent impregnation, and test strip fabrication for medical and industrial applications. The company received FDA 510(k) clearances from total submissions, with all submissions resulting in clearance. Serim's cleared devices focus on gastroenterology and urology applications, including...
