

K971502 SERODIA TP-PANov 13, 1997
203 days to decisionK971502 · Product code: **GMT** · Microbiology
Source: <https://www.510kdatabase.net/k971502/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antigens, Ha, Treponema Pallidum (GMT) |
| Date received | Apr 24, 1997 |
| Decision date | Nov 13, 1997 |
| Days to decision | 203 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Scimedx Tekfile Services |
| Location | Denvill, NJ, US |
| Contact | Gary Lehnus |
| 510(k) history | 1 submissions · 1 cleared · 1997-1997 |

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