

K981498 IS-TOXOPLASMA IGG TEST SYSTEMAug 21, 1998
116 days to decisionK981498 · Product code: **LGD** · Microbiology
Source: <https://www.510kdatabase.net/k981498/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD) |
| Date received | Apr 27, 1998 |
| Decision date | Aug 21, 1998 |
| Days to decision | 116 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Diamedix Corp. |
| Location | Miami, FL, US |
| Contact | LYNNE STIRLING |
| 510(k) history | 68 submissions · 68 cleared · 1986-2011 |

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