

**K012183 BAYER DIAGNOSTICS ADVIA CENTAUR
TOXOPLASMA IGG ASSAY**Dec 27, 2001
168 days to decisionK012183 · Product code: **LGD** · Microbiology
Source: <https://www.510kdatabase.net/k012183/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD) |
| Date received | Jul 12, 2001 |
| Decision date | Dec 27, 2001 |
| Days to decision | 168 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Bayer Diagnostics Corp. |
| Location | Medfield, MA, US |
| Contact | BARBARA PREISEL-SIMMONS |
| 510(k) history | 32 submissions · 32 cleared · 2000-2003 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012183/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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