

**K003291 BAYER DIAGNOSTICS ACS:180 AND ADVIA
CENTAUR ANTI-TPO ASSAY**Dec 5, 2000
46 days to decisionK003291 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k003291/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Thyroid Autoantibody (JZO) |
| Date received | Oct 20, 2000 |
| Decision date | Dec 5, 2000 |
| Days to decision | 46 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003291/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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