

K020807 AFP ASSAY FOR THE ADVIA INTEGRATED MODULAR SYSTEMOct 1, 2002
203 days to decisionK020807 · Product code: **LOJ** · Immunology
Source: <https://www.510kdatabase.net/k020807/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Kit, Test,alpha-fetoprotein For Testicular Cancer (LOJ) |
| Date received | Mar 12, 2002 |
| Decision date | Oct 1, 2002 |
| Days to decision | 203 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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