

K925498 VIDAS ESTRADIOL (E2) ASSAYFeb 12, 1993
105 days to decisionK925498 · Product code: **CHP** · Chemistry
Source: <https://www.510kdatabase.net/k925498/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Estradiol (CHP) |
| Date received | Oct 30, 1992 |
| Decision date | Feb 12, 1993 |
| Days to decision | 105 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Biomerieux Vitek, Inc. |
| Location | Hazelwood, MO, US |
| Contact | VICKI ANASTASI |
| 510(k) history | 49 submissions · 49 cleared · 1992-1998 |

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