FDA 510(k) Premarket Notification

# K896866 LUTEINIZING HORMONE-EIA-XT

**CLEARED**

Feb 13, 1990
69 days to decision

K896866 · Product code: **CEP** · Chemistry
Source: https://www.510kdatabase.net/k896866/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Luteinizing Hormone (CEP) |
| Date received | Dec 6, 1989 |
| Decision date | Feb 13, 1990 |
| Days to decision | 69 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **In Vitro Diagnostics, Inc.** |
| Location | Shelton, CT, US |
| Contact | MUSICK, PH.D. |
| 510(k) history | 15 submissions · 15 cleared · 1985-1990 |