FDA 510(k) Premarket Notification

# K880678 MODIFIED VENTRESCREEN BETA HCG ENZYME IMMUNOASSAY

**CLEARED**

Apr 5, 1988
46 days to decision

K880678 · Product code: **DHA** · Chemistry
Source: https://www.510kdatabase.net/k880678/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Human Chorionic Gonadotropin (DHA) |
| Date received | Feb 19, 1988 |
| Decision date | Apr 5, 1988 |
| Days to decision | 46 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Ventrex Laboratories, Inc.** |
| Location | Mchenry, IL, US |
| Contact | JAMES W CHAMPLIN |
| 510(k) history | 82 submissions · 82 cleared · 1979-1992 |