

K001215 DBEST HCG 2 IU/ML TEST KIT

Jun 22, 2000  
69 days to decision

K001215 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k001215/>

SUBMISSION DETAILS

|                       |                                               |
|-----------------------|-----------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Abbreviated                                   |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received         | Apr 14, 2000                                  |
| Decision date         | Jun 22, 2000                                  |
| Days to decision      | 69 days                                       |
| Third-party review    | No                                            |
| Summary / Statement   | Summary                                       |

APPLICANT

|                |                                         |
|----------------|-----------------------------------------|
| Company        | Ameritek, Inc.                          |
| Location       | Miami, FL, US                           |
| Contact        | K.C. YEE                                |
| 510(k) history | 17 submissions · 17 cleared · 1986-2000 |