

**K000844 ABSOLUTE HCG PREGNANCY TEST**Jun 16, 2000  
93 days to decisionK000844 · Product code: **DHA** · Chemistry  
Source: <https://www.510kdatabase.net/k000844/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Mar 15, 2000
Decision date	Jun 16, 2000
Days to decision	93 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Mizuho USA, Inc.</b>
Location	San Diego, CA, US
Contact	BENEDICT ZIN
510(k) history	7 submissions · 7 cleared · 1993-2006

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000844/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026