

K003856 EZ-HCG URINE(PREGNANCY TEST)Feb 21, 2001
70 days to decisionK003856 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k003856/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Dec 13, 2000
Decision date	Feb 21, 2001
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerica, Inc.
Location	Newport Beach, CA, US
Contact	JAY SINGH
Website	http://www.biomerica.com
510(k) history	10 submissions · 10 cleared · 1991-2023

Biomerica, Inc. is a global biomedical technology company developing, manufacturing, and marketing advanced in-vitro diagnostic products. Headquartered in Irvine, California, the company operates FDA and CE registered manufacturing facilities in California and Mexico, specializing in gastrointestinal and inflammatory disease diagnostics. Biomerica has received FDA 510(k) clearances from total submissions since 1991. The company's cleared devices span chemistry, microbiology, and immunology categories, including pregnancy tests, thyroid function assays, H. pylori detection...
