

K232892 Hp Detect™ Stool Antigen ELISADec 15, 2023
88 days to decisionK232892 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k232892/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Sep 18, 2023
Decision date	Dec 15, 2023
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerica, Inc.
Location	Newport Beach, CA, US
Contact	Bonnie Qiu
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...
