

K900343 GAP-IGGAug 22, 1991
576 days to decisionK900343 · Product code: **LYR** · Microbiology
Source: <https://www.510kdatabase.net/k900343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Jan 23, 1990
Decision date	Aug 22, 1991
Days to decision	576 days
Third-party review	No

APPLICANT

Company	Biomerica, Inc.
Location	Newport Beach, CA, US
Contact	PERRY G RUCKER
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...
