FDA 510(k) Premarket Notification

K915185 GAP IGG H.PYLORI MODIFIED

CLEARED

Mar 4, 1992
107 days to decision

K915185 · Product code: **LYR** · Microbiology
Source: https://www.510kdatabase.net/k915185/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Nov 18, 1991
Decision date	Mar 4, 1992
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

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...