

**K980798 BIOSIGN H. PYLORI WB-NEW ONE-STEP ANTI-H.
PYLORI ANTIBODY TEST**Sep 22, 1998
204 days to decisionK980798 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k980798/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Mar 2, 1998
Decision date	Sep 22, 1998
Days to decision	204 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Princeton BioMeditech Corp.
Location	Monmouth Junction, NJ, US
Contact	JEMO KANG, PH.D.
510(k) history	72 submissions · 72 cleared · 1994-2025

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