

K830497 PEM-TApr 5, 1983
48 days to decisionK830497 · Product code: **JWZ** · Microbiology
Source: <https://www.510kdatabase.net/k830497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Screening, Trichomonas (JWZ)
Date received	Feb 16, 1983
Decision date	Apr 5, 1983
Days to decision	48 days
Third-party review	No

APPLICANT

Company	Hedeco
Location	Mchenry, IL, US
510(k) history	4 submissions · 4 cleared · 1981-1983

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Device record: <https://www.510kdatabase.net/k830497/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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