

K890774 GIARDEIA(TM)Apr 4, 1989
48 days to decisionK890774 · Product code: **KHW** · Microbiology
Source: <https://www.510kdatabase.net/k890774/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Id, Ha, Cep, Entamoeba Histolytica & Rel. Spp. (KHW)
Date received	Feb 15, 1989
Decision date	Apr 4, 1989
Days to decision	48 days
Third-party review	No

APPLICANT

Company	Antibodies, Inc.
Location	Mchenry, IL, US
Contact	BANOVITZ, PH.D.
510(k) history	16 submissions · 16 cleared · 1977-1989

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k890774/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026