FDA 510(k) Premarket Notification

K890774 GIARDEIA(TM)

CLEARED

Apr 4, 1989
48 days to decision

K890774 · 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