FDA 510(k) Premarket Notification

K772219 FIAX TEST FOR ANTI-RUBELLA ANTIBODY

CLEARED

Jan 20, 1978
46 days to decision

K772219 · Product code: **DHN** · Immunology
Source: https://www.510kdatabase.net/k772219/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Dec 5, 1977
Decision date	Jan 20, 1978
Days to decision	46 days
Third-party review	No

APPLICANT

Company	**Idt, A Division of Whittaker M.A. Bioproducts**
Location	Mchenry, IL, US
510(k) history	5 submissions · 5 cleared · 1977-1986