FDA 510(k) Premarket Notification

K882999 RUBENOSTIKA(TM) IGM MICROELISA SYSTEM

CLEARED

Jan 31, 1989
197 days to decision

K882999 · Product code: **LFX** · Microbiology
Source: https://www.510kdatabase.net/k882999/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Jul 18, 1988
Decision date	Jan 31, 1989
Days to decision	197 days
Third-party review	No

APPLICANT

Company	**Organon Teknika Corp.**
Location	Mchenry, IL, US
Contact	TONI M STIFANO
510(k) history	130 submissions · 129 cleared · 1980-2000