

**K863798 FIAX(R) TEST KIT CYTOMEGALOVIRUS M
ANTIBODIES**Apr 14, 1987
197 days to decisionK863798 · Product code: **LKQ** · Microbiology
Source: <https://www.510kdatabase.net/k863798/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibody Igm,if, Cytomegalovirus Virus (LKQ)
Date received	Sep 29, 1986
Decision date	Apr 14, 1987
Days to decision	197 days
Third-party review	No

APPLICANT

Company	Whittaker Bioproducts, Inc.
Location	Walkersville, MD, US
Contact	LOUISE HARRIS
510(k) history	30 submissions · 30 cleared · 1984-1992

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