

K981012 AIA-PACK MYOGLOBIN ASSAYMay 28, 1998
71 days to decisionK981012 · Product code: **DDR** · Immunology
Source: <https://www.510kdatabase.net/k981012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Myoglobin, Antigen, Antiserum, Control (DDR)
Date received	Mar 18, 1998
Decision date	May 28, 1998
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tosoh Medics, Inc.
Location	Washington, DC, US
Contact	LORI ROBINSON
510(k) history	41 submissions · 41 cleared · 1990-2002

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