

K981536 QUANTECH MYOGLOBIN ASSAYJun 29, 1998
61 days to decisionK981536 · Product code: **MVE** · Immunology
Source: <https://www.510kdatabase.net/k981536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biosensor, Immunoassay, Myoglobin (MVE)
Date received	Apr 29, 1998
Decision date	Jun 29, 1998
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hellen Professional Services
Location	Northridge, CA, US
Contact	ROBIN J HELLEN
510(k) history	2 submissions · 2 cleared · 1998-2002

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