

**K961515 QUANTASE PHENYLALANINE ASSAY**Jun 12, 1996  
63 days to decisionK961515 · Product code: **JNB** · Chemistry  
Source: <https://www.510kdatabase.net/k961515/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ninhydrin And L-leucyl-I-alanine (fluorimetric), Phenylalanine (JNB)
Date received	Apr 10, 1996
Decision date	Jun 12, 1996
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Shield Diagnostics, Ltd.</b>
Location	Scotland, KN
Contact	EILEEN MCCAFFERTY
510(k) history	27 submissions · 27 cleared · 1990-2000

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