

K990644 QUANTASE TOTAL GALACTOSE SCREENING ASSAYJun 21, 1999
115 days to decisionK990644 · Product code: **JIA** · Chemistry
Source: <https://www.510kdatabase.net/k990644/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Methods, Galactose (JIA)
Date received	Feb 26, 1999
Decision date	Jun 21, 1999
Days to decision	115 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Quantase , Ltd.
Location	Perth, Scotland, GB
Contact	R. STEWART CAMPBELL
510(k) history	4 submissions · 4 cleared · 1999-2000

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