

**K980574 AURAFLEX TSH-3 200 TEST PACK MODEL NUMBER
80600, AURAFLEX TSH-3 CALIBRATOR PACK MODEL
NUMBER NUMBER 80601 AURAFLEX DILO**Mar 24, 1998
35 days to decisionK980574 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k980574/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Feb 17, 1998
Decision date	Mar 24, 1998
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Alfa Biotech (Uk) , Ltd.
Location	Aldershot, GB
Contact	M J TAYLOR
510(k) history	3 submissions · 3 cleared · 1998-1998

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