

**K970085 SEALITE SCIENCES AQUALITE FSH**Feb 14, 1997  
35 days to decisionK970085 · Product code: **CGJ** · Chemistry  
Source: <https://www.510kdatabase.net/k970085/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Follicle-stimulating Hormone (CGJ)
Date received	Jan 10, 1997
Decision date	Feb 14, 1997
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sealite Sciences, Inc.</b>
Location	Bogart, GA, US
Contact	CATHRYN N CAMBRIA
510(k) history	11 submissions · 11 cleared · 1994-1997

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