

**K970483 AQUALITE INTACT PTH**Apr 14, 1997  
63 days to decisionK970483 · Product code: **CEW** · Chemistry  
Source: <https://www.510kdatabase.net/k970483/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	Feb 10, 1997
Decision date	Apr 14, 1997
Days to decision	63 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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