

**K060348 MODIFICATION TO: TOTAL INTACT PTH  
IMMUNOCHEMILUMINOMETRIC (ICMA) ASSAY KIT**Feb 27, 2006  
17 days to decisionK060348 · Product code: **CEW** · Chemistry  
Source: <https://www.510kdatabase.net/k060348/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	Feb 10, 2006
Decision date	Feb 27, 2006
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Scantibodies Laboratory, Inc.</b>
Location	Santee, CA, US
Contact	MICHAEL NORDSTROM
510(k) history	19 submissions · 19 cleared · 1995-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k060348/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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