

**K004038 TOTAL PTH IMMUNORADIOMETRIC ASSAY(IRMA)
DIAGNOSTIC KIT, MODEL 3KG600**Apr 30, 2001
123 days to decisionK004038 · Product code: **CEW** · Chemistry
Source: <https://www.510kdatabase.net/k004038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	Dec 28, 2000
Decision date	Apr 30, 2001
Days to decision	123 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Scantibodies Laboratory, Inc.
Location	Santee, CA, US
Contact	RICHARD LENART
510(k) history	19 submissions · 19 cleared · 1995-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k004038/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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