

**K944788 INTACT PTH IMMUNORADIOMETRIC (IRMA) ASSAY
(COATED BEAD-TECHNOLOGY)**Jul 19, 1995
294 days to decisionK944788 · Product code: **CEW** · Chemistry
Source: <https://www.510kdatabase.net/k944788/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	Sep 28, 1994
Decision date	Jul 19, 1995
Days to decision	294 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/k944788/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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