K001411 WHOLE PTH (1-84) SPECIFIC IMMUNORADIOMETRIC IRMA DIAGNOSTIC ASSAY KIT, MODEL 3KG056

CLEARED

Aug 21, 2000
109 days to decision

K001411 · Product code: **CEW** · Chemistry
Source: https://www.510kdatabase.net/k001411/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	May 4, 2000
Decision date	Aug 21, 2000
Days to decision	109 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