

K942369 GAMMA-BCT INTACT PTHSep 20, 1994
125 days to decisionK942369 · Product code: **CEW** · Chemistry
Source: <https://www.510kdatabase.net/k942369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	May 18, 1994
Decision date	Sep 20, 1994
Days to decision	125 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Immunodiagnostic Systems , Ltd.
Location	Tyne And Wear, GB
Contact	ANITA GROUNDWATER
510(k) history	23 submissions · 23 cleared · 1994-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942369/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026