

K103325 IDS-ISYS INTACT PTHFeb 3, 2012
448 days to decisionK103325 · Product code: **CEW** · Chemistry
Source: <https://www.510kdatabase.net/k103325/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	Nov 12, 2010
Decision date	Feb 3, 2012
Days to decision	448 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103325/> 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 15, 2026