

K161158 IDS-iSYS Intact PTHNJan 31, 2017
281 days to decisionK161158 · Product code: **CEW** · Chemistry
Source: <https://www.510kdatabase.net/k161158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	Apr 25, 2016
Decision date	Jan 31, 2017
Days to decision	281 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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