

K200475 IDS-iSYS Ostase BAPSep 30, 2020
217 days to decisionK200475 · Product code: **CIN** · Chemistry
Source: <https://www.510kdatabase.net/k200475/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic Separation, Alkaline Phosphatase Isoenzymes (CIN)
Date received	Feb 26, 2020
Decision date	Sep 30, 2020
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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