FDA 510(k) Premarket Notification

CLEARED

K123253 IDS ISYS 1,25 DIHYDROXY VITAMIN D, IDS-ISYS, 1,25 DIHYDROXY VITAMIN D CONTROL SET, AND IDS ISYS 1,25 DIHYDROXY VITAMIN D

Jun 18, 2013
244 days to decision

K123253 · Product code: **MRG** · Chemistry
Source: https://www.510kdatabase.net/k123253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Vitamin D (MRG)
Date received	Oct 17, 2012
Decision date	Jun 18, 2013
Days to decision	244 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.net
Device record: https://www.510kdatabase.net/k123253/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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