

K043125 ORION DIAGNOSTICA UNIQ PINP RIAMay 4, 2005
173 days to decisionK043125 · Product code: **CIN** · Chemistry
Source: <https://www.510kdatabase.net/k043125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic Separation, Alkaline Phosphatase Isoenzymes (CIN)
Date received	Nov 12, 2004
Decision date	May 4, 2005
Days to decision	173 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Orion Diagnostica, OY
Location	Espoo, FI
Contact	ANNIKKA RANTAMA
510(k) history	4 submissions · 4 cleared · 2004-2016

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