

K103484 GSP NEONATAL THYROXINE (T4)Apr 22, 2011
147 days to decisionK103484 · Product code: **KLI** · Chemistry
Source: <https://www.510kdatabase.net/k103484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	Nov 26, 2010
Decision date	Apr 22, 2011
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wallac Oy, A Subsidiary of Perkinelmer, Inc.
Location	Waltham, MA, US
Contact	SUSAN K HAMANN
510(k) history	3 submissions · 3 cleared · 2011-2014

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