

K943416 DELFIA NEONATAL THYROXINE KITMar 10, 1995
238 days to decisionK943416 · Product code: **CDX** · Chemistry
Source: <https://www.510kdatabase.net/k943416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Thyroxine (CDX)
Date received	Jul 15, 1994
Decision date	Mar 10, 1995
Days to decision	238 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Wallac OY
Location	Finland, FI
Contact	GUNNEL LAADSONEN
510(k) history	22 submissions · 21 cleared · 1992-2014

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