

**K001603 REPROBEAD T4 ENZYME IMMUNOASSAY REAGENT
KIT (CATALOG# 105)**Oct 5, 2000
134 days to decisionK001603 · Product code: **KLI** · Chemistry
Source: <https://www.510kdatabase.net/k001603/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	May 24, 2000
Decision date	Oct 5, 2000
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Repromedix Corp.
Location	Woburn, MA, US
Contact	HAN-SOO KIM
510(k) history	3 submissions · 3 cleared · 2000-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001603/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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