

**K001606 REPROBEAD TSH ENZYME IMMUNOASSAY
REAGENT KIT (CATALOG# 107)**Oct 5, 2000
134 days to decisionK001606 · Product code: JLW · Chemistry
Source: <https://www.510kdatabase.net/k001606/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
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

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