

**K081074 DIMENSION TSHL FLEX REAGENT CARTRIDGE AND
TSH SAMPLE DILUENT WITH MODELS RF 612 AND KD691**May 23, 2008
37 days to decisionK081074 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k081074/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Apr 16, 2008
Decision date	May 23, 2008
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	YUK-TING LEWIS
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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