

K143534 Elecsys CA-125 II assayAug 6, 2015
237 days to decisionK143534 · Product code: **LTK** · Immunology
Source: <https://www.510kdatabase.net/k143534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Dec 12, 2014
Decision date	Aug 6, 2015
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Professional Diagnostics
Location	Indianapolis, IN, US
Contact	LINDA MCCAMMACK
510(k) history	2 submissions · 2 cleared · 2010-2015

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