

K052662 ONE STEP FSH MENOPAUSAL TEST

Nov 30, 2005
64 days to decision

K052662 · Product code: **CGJ** · Chemistry
Source: <https://www.510kdatabase.net/k052662/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Follicle-stimulating Hormone (CGJ)
Date received	Sep 27, 2005
Decision date	Nov 30, 2005
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ind Diagnostic, Inc.
Location	Delta, B.C., CA
Contact	JASON PENG
510(k) history	8 submissions · 8 cleared · 2003-2012

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Device record: <https://www.510kdatabase.net/k052662/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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