

**K860984 TANDEM ICON LH ASSAY (URINE)
IMMUNOENZYMETRIC KIT**Apr 29, 1986
43 days to decisionK860984 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k860984/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Mar 17, 1986
Decision date	Apr 29, 1986
Days to decision	43 days
Third-party review	No

APPLICANT

Company	Hybritech, Inc.
Location	Mchenry, IL, US
Contact	BRUNI, PH.D.
510(k) history	63 submissions · 63 cleared · 1981-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k860984/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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