

K895094 TANDEM-E LH IMMUNOENZYMETRIC ASSAY KITOct 31, 1989
78 days to decisionK895094 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k895094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Aug 14, 1989
Decision date	Oct 31, 1989
Days to decision	78 days
Third-party review	No

APPLICANT

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

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