

K894761 TANDEM-E FSH IMMUNOENZYMETRIC ASSAY KITSep 13, 1989
48 days to decisionK894761 · Product code: **CGJ** · Chemistry
Source: <https://www.510kdatabase.net/k894761/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Follicle-stimulating Hormone (CGJ) |
| Date received | Jul 27, 1989 |
| Decision date | Sep 13, 1989 |
| Days to decision | 48 days |
| Third-party review | No |

APPLICANT

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

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