

K863345 TANDEM(R)-M FERRITIN IMMUNOENZYMETRIC ASSAYOct 8, 1986
40 days to decisionK863345 · Product code: **DBF** · Immunology
Source: <https://www.510kdatabase.net/k863345/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ferritin, Antigen, Antiserum, Control (DBF)
Date received	Aug 29, 1986
Decision date	Oct 8, 1986
Days to decision	40 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

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