

K895138 CLINISTAT LDH REAGENT TESTOct 19, 1989
64 days to decisionK895138 · Product code: **CFH** · Chemistry
Source: <https://www.510kdatabase.net/k895138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tetrazolium Int Dye-diaphorase, Lactate Dehydrogenase (CFH)
Date received	Aug 16, 1989
Decision date	Oct 19, 1989
Days to decision	64 days
Third-party review	No

APPLICANT

Company	Heraeus Kulzer, Inc.
Location	Elkhart, IN, US
Contact	ROSANNE SAVOL
510(k) history	145 submissions · 145 cleared · 1988-2009

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