

K885294 BORRELIA BURGENDORFERI IGM ANTIBODY TEST SYSTEMApr 10, 1989
104 days to decisionK885294 · Product code: LSR · Microbiology
Source: <https://www.510kdatabase.net/k885294/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Dec 27, 1988
Decision date	Apr 10, 1989
Days to decision	104 days
Third-party review	No

APPLICANT

Company	Medical Diagnostic Technologies, Inc.
Location	Augusta, GA, US
Contact	DAVID A WALL
510(k) history	57 submissions · 57 cleared · 1985-2006

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