

K952360 CARDIAC STATUS, LIFESIGN MI, VITALSIGN, ACCUSIGN CK-MB/MYOGLOBIN

Aug 14, 1995
103 days to decision

K952360 · Product code: **DDR** · Immunology
Source: <https://www.510kdatabase.net/k952360/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Myoglobin, Antigen, Antiserum, Control (DDR)
Date received	May 3, 1995
Decision date	Aug 14, 1995
Days to decision	103 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Princeton BioMeditech Corp.
Location	Monmouth Junction, NJ, US
Contact	JEMO KANG
510(k) history	72 submissions · 72 cleared · 1994-2025

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Device record: <https://www.510kdatabase.net/k952360/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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