

K971657 ACCURUN 121 HAV IGM POSITIVE CONTROLAug 12, 1997
98 days to decisionK971657 · Product code: **JJY** · Microbiology
Source: <https://www.510kdatabase.net/k971657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	May 6, 1997
Decision date	Aug 12, 1997
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Boston Biomedica, Inc.
Location	West Bridgewater, MA, US
Contact	PATRICIA E GARRETT
510(k) history	12 submissions · 12 cleared · 1997-2003

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