

K972048 ACCURUN 117 HBEAG POSITIVE CONTROLAug 12, 1997
71 days to decisionK972048 · Product code: **JJY** · Microbiology
Source: <https://www.510kdatabase.net/k972048/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Jun 2, 1997
Decision date	Aug 12, 1997
Days to decision	71 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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