

K972307 ACCURUN 119 ANTI-HEPATITIS B E ANTIGEN (ANTI-HBE) POSITIVE CONTROLAug 7, 1997
49 days to decisionK972307 · Product code: JJY · Microbiology
Source: <https://www.510kdatabase.net/k972307/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Jun 19, 1997
Decision date	Aug 7, 1997
Days to decision	49 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972307/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026