

K192380 ST AIA-PACK BNPAug 24, 2020
360 days to decisionK192380 · Product code: **NBC** · Chemistry
Source: <https://www.510kdatabase.net/k192380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Natriuretic Peptide (NBC)
Date received	Aug 30, 2019
Decision date	Aug 24, 2020
Days to decision	360 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujirebio Diagnostics, Inc.
Location	North Caldwell, NJ, US
Contact	Stacey Dolan
510(k) history	45 submissions · 43 cleared · 1989-2025

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