

K211199 ST AIA-PACK BNP AssayNov 8, 2021
200 days to decisionK211199 · Product code: **NBC** · Chemistry
Source: <https://www.510kdatabase.net/k211199/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Natriuretic Peptide (NBC)
Date received	Apr 22, 2021
Decision date	Nov 8, 2021
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tosoh Bioscience, Inc.
Location	Grove City, OH, US
Contact	Louise Musante
510(k) history	20 submissions · 20 cleared · 2007-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211199/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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