

K220163 Her-2, ER, PR IHControlsAug 15, 2022
207 days to decisionK220163 · Product code: **NJW** · Pathology
Source: <https://www.510kdatabase.net/k220163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control Material, Her-2/neu, Immunohistochemistry (NJW)
Date received	Jan 20, 2022
Decision date	Aug 15, 2022
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Cell Standards, Inc.
Location	Sharon, MA, US
Contact	Steven Bogen
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Radcliffe Consulting, Inc.
Contact	Gail E. Radcliffe

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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