FDA 510(k) Premarket Notification

CLEARED

K023335 QCS HER2 IMMUNOCONTROLS (PRODUCT NO. C010)

Jun 18, 2003
254 days to decision

K023335 · Product code: **NJW** · Pathology
Source: https://www.510kdatabase.net/k023335/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control Material, Her-2/neu, Immunohistochemistry (NJW)
Date received	Oct 7, 2002
Decision date	Jun 18, 2003
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Qc Sciences, LLC**
Location	Richmond, VA, US
Contact	JUNQI QIAN
510(k) history	1 submissions · 1 cleared · 2003-2003

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k023335/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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