

K130010 PROSIGNA(TM) BREAST CANCER PROGNOSTIC GENE SIGNATURE ASSAY

Sep 6, 2013
246 days to decision

K130010 · Product code: NYI · Pathology
Source: <https://www.510kdatabase.net/k130010/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Classifier, Prognostic, Recurrence Risk Assessment, Rna Gene Expression, Breast Cancer (NYI)
Date received	Jan 3, 2013
Decision date	Sep 6, 2013
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nanostring Technologies
Location	Seattle, WA, US
Contact	SYLVA KRIZAN, PHD
Website	http://www.nanostring.com
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k130010/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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