

K082150 MODIFICATION TO PAXGENE BLOOD RNA SYSTEMFeb 4, 2009
189 days to decisionK082150 · Product code: **NTW** · Pathology
Source: <https://www.510kdatabase.net/k082150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Blood Collection, Rna Stabilization, Rna Purification, Rt-pcr Molecular Diagnostic Test (NTW)
Date received	Jul 30, 2008
Decision date	Feb 4, 2009
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Preanalytix GmbH
Location	Franklin Lakes, NJ, US
Contact	WENDY BALLESTEROS
510(k) history	4 submissions · 3 cleared · 2005-2023

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