FDA 510(k) Premarket Notification

CLEARED

K200009 Adaptive Biotechnologies clonoSEQ Assay

Aug 5, 2020
216 days to decision

K200009 · Product code: **QDC** · Medical Genetics
Source: https://www.510kdatabase.net/k200009/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-based Test For Minimal Residual Disease For Hematologic Malignancies (QDC)
Date received	Jan 2, 2020
Decision date	Aug 5, 2020
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Adaptive Biotechnologies Corporation**
Location	Seattle, WA, US
Contact	Megan Duncan
510(k) history	2 submissions · 1 cleared · 2018-2020