FDA 510(k) Premarket Notification

**CLEARED**

# K173492 MRDx BCR-ABL Test, MRDx BCR-ABL Test Software

Dec 22, 2017
39 days to decision

K173492 · Product code: **OYX** · Pathology
Source: https://www.510kdatabase.net/k173492/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent - SD |
| Submission type | Traditional |
| Device classification | Bcr/abl1 Monitoring Test (OYX) |
| Date received | Nov 13, 2017 |
| Decision date | Dec 22, 2017 |
| Days to decision | 39 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **MolecularMD Corporation** |
| Location | Portland, OR, US |
| Contact | Kevin Hawkins |
| 510(k) history | 1 submissions · 0 cleared · 2017-2017 |