

K191550 BroncholabMar 4, 2020
266 days to decisionK191550 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k191550/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received | Jun 12, 2019 |
| Decision date | Mar 4, 2020 |
| Days to decision | 266 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Fluidda, Inc. |
| Location | West Hollywood, CA, US |
| Contact | Anjali Nair |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191550/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026