

K243396 Aptima SARS-CoV-2 AssayFeb 13, 2025
105 days to decisionK243396 · Product code: **QQX** · Microbiology
Source: <https://www.510kdatabase.net/k243396/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Respiratory Specimen Nucleic Acid Sars-cov-2 Test (QQX) |
| Date received | Oct 31, 2024 |
| Decision date | Feb 13, 2025 |
| Days to decision | 105 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Hologic, Inc. |
| Location | Waltham, MA, US |
| Contact | Katerina Capkova |
| Website | https://www.hologic.com/ |
| 510(k) history | 115 submissions · 111 cleared · 1987-2025 |

Hologic, Inc. is a medical device company headquartered in Waltham, Massachusetts. The company specializes in women's health, diagnostics, and medical imaging technologies. Hologic has maintained a strong FDA 510(k) regulatory record since its founding in 1987. The company has received FDA 510(k) clearances from total submissions. Recent cleared devices span microbiology, radiology, and obstetrics & gynecology categories. The latest clearance in 2025 demonstrates continued active development and regulatory engagement. Hologic's cleared device portfolio includes molecular ...

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Device record: <https://www.510kdatabase.net/k243396/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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