

K201269 Accula Strep A TestNov 9, 2020
181 days to decisionK201269 · Product code: **PGX** · Microbiology
Source: <https://www.510kdatabase.net/k201269/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Dual Track |
| Device classification | Groups A, C And G Beta-hemolytic Streptococcus Nucleic Acid Amplification System (PGX) |
| Date received | May 12, 2020 |
| Decision date | Nov 9, 2020 |
| Days to decision | 181 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Mesa Biotech, Inc. |
| Location | San Diego, CA, US |
| Contact | Barbara Stevens |
| 510(k) history | 3 submissions · 3 cleared · 2018-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201269/> 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