

K161258 NOVA Lite DAPI ANCA Ethanol Kit, NOVA Lite DAPI ANCA Formalin KitFeb 3, 2017
275 days to decisionK161258 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k161258/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB) |
| Date received | May 4, 2016 |
| Decision date | Feb 3, 2017 |
| Days to decision | 275 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Inova Diagnostics, Inc. |
| Location | San Diego, CA, US |
| Contact | Gabriella Lakos |
| Website | https://www.inovadx.com |
| 510(k) history | 138 submissions · 136 cleared · 1988-2026 |

Siemens Healthcare Diagnostics, Inc. is a leading diagnostic device manufacturer based in New York. The company specializes in laboratory diagnostics and clinical chemistry solutions. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2008. Chemistry devices and immunology assays represent the core focus of its regulatory portfolio. The latest FDA 510(k) clearance in 2026 reflects continued active development and market engagement. Recent cleared devices include automated chemistry analyzers, immunoassay systems, and special...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161258/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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