

K172416 Synermed Opiate Enzyme ImmunoassayApr 19, 2018
252 days to decisionK172416 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k172416/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Opiates (DJG) |
| Date received | Aug 10, 2017 |
| Decision date | Apr 19, 2018 |
| Days to decision | 252 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Infrared Laboratory Systems, LLC (Dbn Synermed) |
| Location | Westfield, IN, US |
| Contact | Julie Paschal |
| 510(k) history | 3 submissions · 3 cleared · 2016-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172416/> 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 May 30, 2026