

**K180202 Histofluor Rodent LKS Fluorescent Antibody Test System, Image Navigator by Immuno Concepts**Oct 19, 2018  
268 days to decisionK180202 · Product code: **DBL** · Immunology  
Source: <https://www.510kdatabase.net/k180202/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Multiple Autoantibodies, Indirect Immunofluorescent, Antigen, Control (DBL) |
| Date received         | Jan 24, 2018  |
| Decision date         | Oct 19, 2018  |
| Days to decision      | 268 days  |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Immuno Concepts, N.A. , Ltd.</b>   |
| Location       | Dallas, TX, US                        |
| Contact        | Eric S Hoy                            |
| 510(k) history | 4 submissions · 4 cleared · 2003-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180202/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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