

**K201069 VibrantVue Scleral Saline**Jul 31, 2020  
100 days to decisionK201069 · Product code: **MRC** · Ophthalmic  
Source: <https://www.510kdatabase.net/k201069/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Products, Contact Lens Care, Rigid Gas Permeable (MRC) |
| Date received         | Apr 22, 2020   |
| Decision date         | Jul 31, 2020   |
| Days to decision      | 100 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Dry Eye Innovations, LLC</b>       |
| Location       | Oak Brook, IL, US                     |
| Contact        | Donald R. Sanders                     |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

**REGULATORY CONSULTANT**

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|-----------------|--------------------------------|
| Consulting firm | <b>Eyereg Consulting, Inc.</b> |
| Contact         | Bret Andre                     |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201069/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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