

**K200242 StaClear Syringe**Jul 27, 2020  
178 days to decisionK200242 · Product code: **QLY** · General Hospital  
Source: <https://www.510kdatabase.net/k200242/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Ophthalmic Syringe (QLY)           |
| Date received         | Jan 31, 2020                       |
| Decision date         | Jul 27, 2020                       |
| Days to decision      | 178 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Tribofilm Research, Inc.</b>       |
| Location       | Raleigh, NC, US                       |
| Contact        | Jackson Thornton                      |
| 510(k) history | 2 submissions · 2 cleared · 2007-2020 |

**REGULATORY CONSULTANT**

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|-----------------|------------------|
| Consulting firm | <b>Namsa</b>     |
| Contact         | Beryl St. Jeanne |

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/k200242/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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