

**K202081 Biodegradable DriTek Powder Free Nitrile Examination Glove, Low Dermatitis Potential Claim, Blue**Mar 19, 2021  
235 days to decisionK202081 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k202081/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received         | Jul 27, 2020                            |
| Decision date         | Mar 19, 2021                            |
| Days to decision      | 235 days                                |
| Third-party review    | No                                      |
| Combination product   | No                                      |
| PCCP authorized       | No                                      |
| Summary / Statement   | Statement                               |

**APPLICANT**

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|----------------|---|
| Company        | <b>Shen Wei (Usa), Inc.</b>             |
| Location       | Foster City, CA, US                     |
| Contact        | Cheryl Reep                             |
| 510(k) history | 58 submissions · 58 cleared · 1989-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202081/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026