

**K942022 FACE-IT SHIELD**Jul 8, 1994  
73 days to decisionK942022 · Product code: **LYU** · General Hospital  
Source: <https://www.510kdatabase.net/k942022/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Accessory, Surgical Apparel (LYU)  |
| Date received         | Apr 26, 1994                       |
| Decision date         | Jul 8, 1994                        |
| Days to decision      | 73 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Onyx Medical Corp.</b>               |
| Location       | Memphis, TN, US                         |
| Contact        | ROGER MACHSON                           |
| 510(k) history | 47 submissions · 22 cleared · 1990-1994 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k942022/> 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 22, 2026