

**K201479 DemeMASK**Jul 24, 2020  
50 days to decisionK201479 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k201479/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Abbreviated                        |
| Device classification | Mask, Surgical (FXX)               |
| Date received         | Jun 4, 2020                        |
| Decision date         | Jul 24, 2020                       |
| Days to decision      | 50 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Demetech Corporation</b>           |
| Location       | Miami Lakes, FL, US                   |
| Contact        | Tracy Chadwick                        |
| 510(k) history | 5 submissions · 5 cleared · 2018-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201479/> 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 June 24, 2026