

# K192978 EOGas 4 Ethylene Oxide Gas Sterilizer

Nov 12, 2020  
385 days to decision

K192978 · Product code: **FLF** · General Hospital  
Source: <https://www.510kdatabase.net/k192978/>

## SUBMISSION DETAILS

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Sterilizer, Ethylene-oxide Gas (FLF) |
| Date received         | Oct 24, 2019                         |
| Decision date         | Nov 12, 2020                         |
| Days to decision      | 385 days                             |
| Third-party review    | No                                   |
| Combination product   | No                                   |
| PCCP authorized       | No                                   |
| Summary / Statement   | Summary                              |

## APPLICANT

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|                |   |
|----------------|---|
| Company        | <b>Andersen Sterilizers, Inc.</b>       |
| Location       | Haw River, NC, US                       |
| Contact        | William K. Andersen                     |
| 510(k) history | 19 submissions · 19 cleared · 2015-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k192978/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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