

**K974090 95 C/1.5 CITRIC ACID HEAT PROCESSING OF  
POLYSULFONE DIALYZERS**Aug 27, 1998  
302 days to decisionK974090 · Product code: **MSE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k974090/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Hemodialyzer, Re-use, Low Flux (MSE) |
| Date received         | Oct 29, 1997                         |
| Decision date         | Aug 27, 1998                         |
| Days to decision      | 302 days                             |
| Third-party review    | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Fresenius Medical Care North America</b> |
| Location       | Lexington, MA, US                           |
| Contact        | TOM FOLDEN                                  |
| 510(k) history | 43 submissions · 43 cleared · 1998-2025     |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974090/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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