

**K874549 NEPHROSS I.Q. ANDANTE**Jan 29, 1988  
86 days to decisionK874549 · Product code: **FJI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k874549/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Dialyzer, Capillary, Hollow Fiber (FJI) |
| Date received         | Nov 4, 1987                             |
| Decision date         | Jan 29, 1988                            |
| Days to decision      | 86 days                                 |
| Third-party review    | No                                      |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Organon Teknika Corp.</b>              |
| Location       | Mchenry, IL, US                           |
| Contact        | SHELDON MAZURSKY                          |
| 510(k) history | 130 submissions · 129 cleared · 1980-2000 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k874549/>; 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