

**K895244 MODIFIED LABELING TO MODEL 9608 ARTERIAL  
HEMO BLD.**Feb 12, 1990  
175 days to decisionK895244 · Product code: **KOC** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k895244/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | Accessories, Blood Circuit, Hemodialysis (KOC) |
| Date received         | Aug 21, 1989                                   |
| Decision date         | Feb 12, 1990                                   |
| Days to decision      | 175 days                                       |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>National Medical Care, Medical Products Div., Inc.</b> |
| Location       | Rockleigh, NJ, US   |
| Contact        | BERGER, PHD   |
| 510(k) history | 62 submissions · 62 cleared · 1985-1996                   |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k895244/>; 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 30, 2026