

**K801451 ISONEPHROS-PEDIATRIC, STANDARD, OPTIMUM**Sep 26, 1980  
95 days to decisionK801451 · Product code: **FJG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k801451/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Parallel Flow (FJG)
Date received	Jun 23, 1980
Decision date	Sep 26, 1980
Days to decision	95 days
Third-party review	No

**APPLICANT**

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Company	<b>Medical, Inc.</b>
Location	Walker, MI, US
510(k) history	21 submissions · 20 cleared · 1977-1993

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

Device record: <https://www.510kdatabase.net/k801451/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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