

**K002816 TRANSONIC HEMODIALYSIS FLOW REVERSER,
MODEL B FLOWREV**

Nov 22, 2000
72 days to decision

K002816 · Product code: **KOC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k002816/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Blood Circuit, Hemodialysis (KOC)
Date received	Sep 11, 2000
Decision date	Nov 22, 2000
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Transonic Systems, Inc.
Location	Ithaca, NY, US
Contact	MARK S ALSBERGE
510(k) history	16 submissions · 16 cleared · 1988-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k002816/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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