

K001971 HEMODIALYSIS TUBING SETSMay 24, 2001
330 days to decisionK001971 · Product code: **FIB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k001971/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Protector, Transducer, Dialysis (FIB)
Date received	Jun 28, 2000
Decision date	May 24, 2001
Days to decision	330 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ofi Biomedica S.P.A.
Location	North Attleboro, MA, US
Contact	MARY MCNAMARA-CULLINANE
510(k) history	1 submissions · 1 cleared · 2001-2001

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