

**K030348 BIOPURE PORTABLE RO SYSTEM, BIOPURE 4400
SERIES RO SYSTEM, BIOPURE 8400 SERIES RO
SYSTEM, BIOPURE WATER PURIFICATION PRETRE**Oct 21, 2003
260 days to decisionK030348 · Product code: **FIP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k030348/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Feb 3, 2003
Decision date	Oct 21, 2003
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biolab Equipment Canada , Ltd.
Location	Thornhill, Ontario, CA
Contact	JERRY PONIKVAR
510(k) history	1 submissions · 1 cleared · 2003-2003

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