

**K945543 GAMGRO ENGSTROM Y FILTER WITH EDITH FLEX
(1500 F), EDIT 500, 1000, 2600 AND Y FILTER PACKAGED
ALONE**Nov 29, 1994
15 days to decisionK945543 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k945543/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Nov 14, 1994
Decision date	Nov 29, 1994
Days to decision	15 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Intersect Medical Products, Inc.
Location	Mchenry, IL, US
Contact	JEFFREY R SHIDEMAN
510(k) history	5 submissions · 5 cleared · 1979-1994

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