

K912347 BIPURE 1000Sep 23, 1991
118 days to decisionK912347 · Product code: **FYD** · General Hospital
Source: <https://www.510kdatabase.net/k912347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Exhaust, Surgical (FYD)
Date received	May 28, 1991
Decision date	Sep 23, 1991
Days to decision	118 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Laser Engineering, Inc.
Location	Milford, MA, US
Contact	ROBERT I.RUDKO
510(k) history	18 submissions · 18 cleared · 1988-2022

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