

K002946 SILENT BIOPSY NEEDLEDec 19, 2000
89 days to decisionK002946 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k002946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Sep 21, 2000
Decision date	Dec 19, 2000
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	H.S. Hospital Service S.R.L.
Location	South Glastonbury, CT, US
Contact	LUCIO IMPROTA
510(k) history	6 submissions · 6 cleared · 2000-2002

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