

K131925 HS NOTAOct 10, 2014
471 days to decisionK131925 · Product code: **FCG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k131925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Jun 26, 2013
Decision date	Oct 10, 2014
Days to decision	471 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	H.S. Hospital Services S.P.A.
Location	Boca Raton, FL, US
Contact	LUCIO IMPROTA
510(k) history	4 submissions · 4 cleared · 2001-2014

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