

**K013070 JAMSHIDI BIOPSY NEEDLE**Dec 12, 2001  
90 days to decisionK013070 · Product code: **FCG** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k013070/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Sep 13, 2001
Decision date	Dec 12, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013070/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 6, 2026