

K010735 SPEEDYBELLAug 17, 2001
158 days to decisionK010735 · Product code: **KNW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k010735/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Mar 12, 2001
Decision date	Aug 17, 2001
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biopsybell S.A.S.
Location	South Glastonbury, CT, US
Contact	LUCIO IMPROTA
510(k) history	3 submissions · 3 cleared · 2001-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010735/> Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026