

**K011575 22MM SITESELECT BREAST BIOPSY DEVICE MODEL
SSD022**Aug 17, 2001
87 days to decisionK011575 · Product code: **KNW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k011575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	May 22, 2001
Decision date	Aug 17, 2001
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Imagyn Surgical
Location	Richland, MI, US
Contact	JULIE POWELL
510(k) history	3 submissions · 2 cleared · 1999-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011575/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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