FDA 510(k) Premarket Notification

K013109 SONOPSY

CLEARED

Mar 12, 2002
176 days to decision

K013109 · Product code: **FCG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k013109/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Sep 17, 2001
Decision date	Mar 12, 2002
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hakko Medical Co., Ltd.**
Location	Meguro-Ku, Tokyo, JP
Contact	SHIRO JITAGAWA
510(k) history	3 submissions · 3 cleared · 2002-2003

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k013109/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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