FDA 510(k) Premarket Notification

K010735 SPEEDYBELL

CLEARED

Aug 17, 2001
158 days to decision

K010735 · 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