FDA 510(k) Premarket Notification

K180363 Clear-Tip EUS-FNA

CLEARED

Nov 1, 2018
265 days to decision

K180363 · Product code: **FCG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k180363/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Feb 9, 2018
Decision date	Nov 1, 2018
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Finemedix Co., Ltd.**
Location	Daegu, KR
Contact	Heon Sik Lee
510(k) history	11 submissions · 11 cleared · 2018-2026