

K171956 Sterile Endoscope Biopsy Sampling NeedleDec 12, 2017
166 days to decisionK171956 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k171956/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Jun 29, 2017
Decision date	Dec 12, 2017
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Detain Medical Devices Co., Ltd.
Location	Changzhou, CN
Contact	Zhengrong Ding
510(k) history	1 submissions · 1 cleared · 2017-2017

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