

K181756 Gangi-SoftGuard Coaxial Needle, Gangi-HydroGuard Coaxial NeedleDec 18, 2018
169 days to decisionK181756 · Product code: **FCG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k181756/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Jul 2, 2018
Decision date	Dec 18, 2018
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Apriomed AB
Location	Uppsala, SE
Contact	Katrin Svensson
510(k) history	3 submissions · 3 cleared · 2015-2020

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