

**K081323 BIOPSY GUIDE KIT FOR 8808 AND BIPLANE, ENDFIRE
AND DUAL BIOPSY GUIDES FOR 8818**Jul 22, 2008
71 days to decisionK081323 · Product code: **FCG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k081323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	May 12, 2008
Decision date	Jul 22, 2008
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	B-K Medical Aps
Location	Herlev, DK
Contact	JENS RASMUSSEN
510(k) history	11 submissions · 11 cleared · 2007-2014

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