

K161409 M-Biopsy Semi-Automatic Biopsy Instrument M-Biopsy Coaxial Introducer Needle for SemAug 2, 2016
74 days to decisionK161409 · Product code: **KNW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k161409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	May 20, 2016
Decision date	Aug 2, 2016
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mermaid Medical A/S
Location	Stenloese, DK
Contact	Pia Wissing Jensen
510(k) history	1 submissions · 1 cleared · 2016-2016

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