

**K080095 CORAMATE/SPIROTOME SYSTEM**Apr 11, 2008  
88 days to decisionK080095 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k080095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jan 14, 2008
Decision date	Apr 11, 2008
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medinvents</b>
Location	Hasselt, Limburg, BE
Contact	JAAK JANSSENS
510(k) history	2 submissions · 2 cleared · 2006-2008

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