

**K190512 SmartBand EMR Kit, SmartBand EMR Pack, SmartSnare**

Nov 22, 2019  
266 days to decision

K190512 · Product code: **FDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k190512/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Snare, Flexible (FDI)
Date received	Mar 1, 2019
Decision date	Nov 22, 2019
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intelligent Endoscopy</b>
Location	Clemmons, NC, US
Contact	Melissa Clark
510(k) history	1 submissions · 1 cleared · 2019-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k190512/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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