

**K211309 endomina system**Dec 7, 2021  
221 days to decisionK211309 · Product code: **OCW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k211309/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Tissue Approximation Device (OCW)
Date received	Apr 30, 2021
Decision date	Dec 7, 2021
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Endo Tools Therapeutics S.A.</b>
Location	Gosselies, BE
Contact	Marine Rouyer
Website	<a href="https://www.endotools.be">https://www.endotools.be</a>
510(k) history	2 submissions · 2 cleared · 2021-2026

Endo Tools Therapeutics S.A. is dedicated to developing innovative endoscopic devices for gastric and urological conditions. Based in Gosselies, Belgium, the company focuses on minimally invasive therapeutic interventions using natural orifice access. The endomina® system represents their core technology, enabling endoscopic suturing and tissue approximation procedures. The company has received FDA 510(k) clearances from total submissions since 2021. All submissions focus on Gastroenterology & Urology devices. The latest clearance in 2026 demonstrates continued regulatory...