

**K221608 NaviCam Capsule Endoscope System with NaviCam Stomach Capsule and NaviCam Tether, NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Stomach Capsule and NaviCam Tether**

Nov 22, 2022  
172 days to decision

K221608 · Product code: **QKZ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k221608/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Magnetically Maneuvered Capsule Endoscopy System (QKZ)
Date received	Jun 3, 2022
Decision date	Nov 22, 2022
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Anx Robotica Corp</b>
Location	Plano, TX, US
Contact	Tim Thomas
510(k) history	6 submissions · 6 cleared · 2019-2024

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

Device record: <https://www.510kdatabase.net/k221608/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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