

K231960 NaviCam Xpress Stomach Capsule Endoscope System (NaviCam Xpress Stomach System) with NaviCam Capsule and NaviCam Tether

Oct 3, 2023
92 days to decision

K231960 · Product code: **QKZ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k231960/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Magnetically Maneuvered Capsule Endoscopy System (QKZ)
Date received	Jul 3, 2023
Decision date	Oct 3, 2023
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anx Robotica Corporation
Location	Plano, TX, US
Contact	Tim Thomas
510(k) history	3 submissions · 3 cleared · 2023-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k231960/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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