FDA 510(k) Premarket Notification

K221590 NaviCam Small Bowel Capsule Endoscopy System

CLEARED

Dec 2, 2022
183 days to decision

K221590 · Product code: **NEZ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k221590/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Jun 2, 2022
Decision date	Dec 2, 2022
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ankon Technologies Co., Ltd.**
Location	Wuhan, CN
Contact	Si Feng Wang
510(k) history	2 submissions · 1 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**ProMedoss, Inc.**
Contact	Shoshana Friedman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT05086471

Performance Evaluation of the NaviCam SB Capsule Endoscope System for the Diagnosis of Small Bowel Diseases

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	87 patients (actual)
Study sites	1 site
Condition studied	Small Bowel Disease
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 30, 2021
Sponsor	Union Hospital, Tongji Medical College, Huazhong University of Science and Technology (Other)

Primary outcome

Diagnostic agreement rate

Secondary outcome

Intestinal transit time

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05086471