

**DE NOVO CLASSIFICATION REQUEST FOR
NAVICAM CAPSULE ENDOSCOPE SYSTEM WITH NAVICAM STOMACH CAPSULE**

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Magnetically maneuvered capsule endoscopy system. A magnetically maneuvered capsule endoscopy system consists of an ingestible capsule and magnetic controller and is used for visualization of the stomach and duodenum. The ingestible capsule contains a camera that wirelessly captures images of the mucosa. The magnetic controller is used outside of the patient and is magnetically coupled with the capsule to control its location and viewing direction.

NEW REGULATION NUMBER: 21 CFR 876.1310

CLASSIFICATION: Class II

PRODUCT CODE: QKZ

BACKGROUND

DEVICE NAME: NaviCam Capsule Endoscope System with NaviCam Stomach Capsule

SUBMISSION NUMBER: DEN190037

DATE DE NOVO RECEIVED: August 13, 2019

SPONSOR INFORMATION:

AnX Robotica, Inc.
8 The Green, STE A
Dover, DE 19901

INDICATIONS FOR USE

The NaviCam Stomach Capsule is intended for visualization of the stomach of adults (≥ 22 years old) with a BMI less than 38. The system can be used in clinics and hospitals, including ER settings.

LIMITATIONS

The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR §801.109.

Limitations on device use are also achieved through the following statements included in the Instructions for Use Manual:

Capsule endoscopy (CE) is intended to provide visualization of the stomach and duodenal bulb. The device is not intended as a treatment. The advantage of this device is that it is minimally invasive and without sedation.

The primary risks of the NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule are the possibilities of false positive and false negative results. Patients with a false negative CE result would not be identified as having cancerous lesions or abnormalities that would require subsequent treatment. Patients with a false positive CE result may be advised to undergo unnecessary additional evaluation.

Undergoing an MRI while the NaviCam Stomach Capsule is inside the patient's body may cause damage to the intestinal tract or abdominal cavity. If the patient did not positively verify the excretion of the NaviCam Stomach Capsule from the body, contact the physician for evaluation and possible abdominal X-ray before undergoing an MRI examination.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule is an endoscopic capsule imaging system intended to obtain images of the stomach and duodenum. In contrast to passive capsule endoscopy systems, it uses external magnetic fields to allow the position of the capsule to be controlled by an operator. The NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule consists of an ingestible capsule, a data recorder, a locator, and a controller.

CAPSULE

The NaviCam Stomach Capsule (AKEM-11SW) is an ingestible imaging device having an outer diameter of 12 mm and a total length of 28 mm. See image of the capsule below.



Figure 3-2: NaviCam Stomach Capsule

The capsule captures images via a Complementary Metal-Oxide Semiconductor (CMOS) sensor. A clear top cover contains a compact objective lens in front of the CMOS. Light-emitting diodes (LEDs) and a photoresistor are allocated around the objective lens. It consists of radiofrequency

(RF) transmitter and an antenna for radio transmission. The capsule is powered by two silver oxide batteries.

DATA RECORDER

The data recorder (AKR-1) is a portable data receiving unit powered by a built-in rechargeable lithium battery, which is placed inside an examination vest worn by the patient during examination. It is used to receive image data wirelessly transmitted from the capsule. See image of the data recorder in Figure 3-3 and image of the data recorder in the examination vest in Figure 3-4 below.

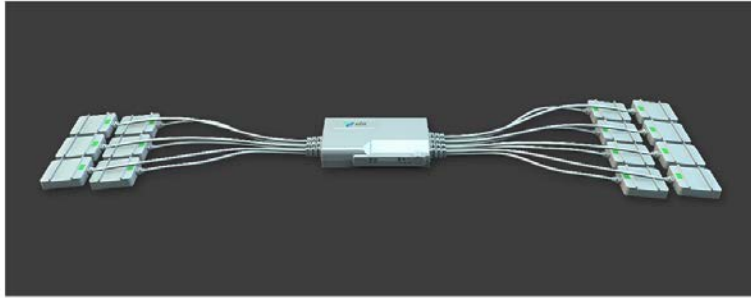


Figure 3-3: NaviCam Data Recorder



Figure 3-4: NaviCam Data Recorder in Examination Vest

LOCATOR

The locator (AKS-1) is a portable magnetic scanning device powered by a built-in rechargeable lithium battery. It is used to detect whether the capsule is inside the human body and probe its approximate position. Also, it is used to turn on the capsule before the patient ingests the capsule. See image of the locator below.



Figure 3-7: NaviCam Locator

CONTROLLER

The controller (NaviEC-1000) allows the position of the capsule to be moved in three-dimensional space and is comprised of the following core components:

- Console
- Translational rotation platform
- Magnetic ball
- Examination bed



Figure 3-5: NaviCam Controller

SUMMARY OF NONCLINICAL/BENCH STUDIES

Non-clinical/bench studies conducted on the NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule device contribute to a demonstration of a reasonable assurance of safety and effectiveness of the device and are summarized below.

BIOCOMPATIBILITY/MATERIALS

The patient contacting component of the NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule is the NaviCam Stomach Capsule. The capsule was evaluated with respect to its intended use per ISO 10993-1:2003, Biological evaluation of medical devices and FDA Guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process’”. Testing was performed on final finished devices. The following tests were performed on the NaviCam Stomach Capsule.

- Cytotoxicity
- Sensitization
- Irritation

The results supported the biocompatibility of the NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule.

SHELF LIFE/STERILITY

The NaviCam Stomach Capsule is provided sterile. Sterilization was evaluated for conformance to ANSI/ AAMI/ ISO 11135:2014 Sterilization of health care products- Ethylene oxide- Requirements for development, validation and routine control of a sterilization process for medical devices. The expected shelf life for the NaviCam Stomach Capsule is 14 months, based on the clinical and non-clinical testing.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

Electromagnetic Compatibility (EMC):

The NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule was evaluated for conformance to IEC 60601-1-2:2014 and was found to comply with all applicable requirements of this EMC testing standard.

Electrical Safety:

The NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule was evaluated for conformance to ANSI/AAMI ES60601-1:2015 (general requirements). Review of the results concluded that the device complies with all the electrical safety requirements specified in this standard.

SOFTWARE

The NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule software functions to communicate with the NaviCam Data Recorder and to collect data from the capsule and send information to the console.

The software/firmware was reviewed according to the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005. The software has a moderate level of concern.

HUMAN FACTORS

The NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule was evaluated per FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices". The summative study aimed to assess the users' ability to operate the NaviCam Capsule Endoscope System with the NaviCam Stomach Capsule, to evaluate

the adequacy of the training session to be provided to new users, and to detect the possibility of misuse. All participants received basic training and the User Manual then they were asked to perform a series of simulated use tasks using the complete system and a stomach model. The number of attempts to successfully complete the tasks were recorded by dedicated individuals. Upon completion of the tasks, each participant was requested to complete a system usability scale (SUS) questionnaire. A total of fifteen physicians from a variety of backgrounds, years of practicing medicine and experience with capsule endoscopy participated in the study. All 15 physicians successfully performed all tasks in either first or second attempt without asking for clarification or assistance. The performance goals were successfully met demonstrating that the NaviCam Capsule Endoscope System with the NaviCam Stomach Capsule can be safely and effectively use by representative users without producing patterns of failures that could result in negative clinical impact or injury to patients and users.

PERFORMANCE TESTING- BENCH

Non-clinical performance tests were conducted to demonstrate mechanical integrity and functionality of the NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule. The table below (Table 1) summarizes each of these bench tests, which included appropriate acceptance criteria for the intended use of the device.

Table 1. Non-Clinical Completed Testing

Test	Purpose	Acceptance Criteria	Results
Bite Force	Testing was performed to determine if the NaviCam capsule can withstand applied force in case of accidental biting.	The capsule should withstand applied force up to (b) (4)	Passed
Temperature Safety	Testing was performed to determine the temperature change during NaviCam capsule operation.	ΔT should not be more than (b) (4).	Passed
Magnetic Force Measurement	Testing was performed to measure the maximum value of magnetic flux density on the surface of the NaviCam capsule.	The acceptance criteria for this test are: (b) (4)	Passed
Magnetic Field Test	Testing was performed to determine the magnetic field safety distance of the capsule.	1) The maximum value of magnetic flux density on the surface of the NaviCam stomach capsule must be less than or equal to (b) (4) 2) The magnetic field of the capsule at (b) (4) must be less than (b) (4).	Passed

Battery Life	Testing was performed to determine the use life of the battery.	The acceptable result of the battery test is at least (b) (4) pictures (equal to (b) (4) hours battery life time, (b) (4) captured by the capsule.	Passed
pH Test	Testing was performed to evaluate the integrity of the NaviCam capsule during exposure to extreme pH levels.	1) After soaking, there is no change in the capsule weight. Considering measurement error, the variation in weights obtained by the balance shall not exceed (b) (4). 2) After soaking, there is no change on the surface of the capsule front and rear shells. 3) Resolution and color reproduction are not affected.	Passed
Color Performance	Testing was performed to evaluate the color reproductive performance of NaviCam capsule.	For a capsule endoscope, because of its size, Field of View (FOV), small field size and the way of imaging based on the illumination of its built-in LEDs, for improved image color reproduction the total color difference of a sample (ΔE) should be kept as no more than (b) (4).	Passed
Image Resolution	Testing was performed to evaluate the image resolution of the NaviCam capsule.	For (b) (4) working distance, module transfer function (MTF) (b) (4) is not less than (b) (4) (b) (4)	Passed
Field of View	Testing was performed to determine the FOV value of the NaviCam capsule.	(b) (4) is accepted, that is (b) (4) (b) (4) degree.	Passed
Geometric Distortion	Testing was performed to determine geometric distortion of the NaviCam capsule and provide the local magnification of the image.	Distortion value not larger than (b) (4) is accepted.	Passed
Depth of View (DOV)	Testing was performed to measure the MTF in air and underwater at (b) (4) different working distances within the	For reflectance USAF1951 angular resolution test, DOV is (b) (4) mm to (b) (4) in air or under water.	Passed

	claimed DOV range (b) (4) using ISO 12233 slanted edge methodology and to verify the claimed DOV range (b) (4) in air and under water using angular resolution method.		
Peak Illuminance	Testing was performed to determine peak illuminance value of capsule endoscope to evaluate sufficient illuminance from the capsule.	(b) (4) is accepted, that is (b) (4) to (b) (4) lux.	Passed
Image Intensity Uniformity (IIU)	Testing was performed to demonstrate the IIU property of optical performance	(1) The two-dimensional distribution of the IIU space is basically a spatially symmetric distribution. (2) The four-dimensional distribution of the IIU at (b) (4) (b) (4) is basically symmetrical from the center. (3) The calculated minimum IIU value in the four directions of (b) (4) (b) (4) should not be less than (b) (4).	Passed
Photobiological Safety	The testing was performed to determine optical safety based on maximum (worst-case) light exposure to internal gastrointestinal mucosa, and cover ultraviolet, visible, and near-infrared ranges, as appropriate.	The device must meet light hazard exposure limits per IEC 62471:2006.	Passed

SUMMARY OF CLINICAL INFORMATION

Clinical data from two clinical studies and 11 articles published in scientific journals were leveraged to evaluate the safety and effectiveness of the NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule.

COMPARATIVE STUDY

In a multicenter blinded study, magnetic capsule endoscopy (MCE) was compared with conventional gastroscopy in 350 patients with upper abdominal complaints scheduled to undergo gastroscopy at a tertiary center in China.¹ In the study, clinicians first used the MCE system to

¹ Liao, Z., et al., *Accuracy of Magnetically Controlled Capsule Endoscopy, Compared With Conventional Gastroscopy, in Detection of Gastric Diseases*. Clin Gastroenterol Hepatol, 2016. 14(9): p. 1266-1273.e1.

perform CE on the subjects. Then after 2 hours the subjects underwent gastroscopy. Gastroscopy results were used as the gold standard or control in the trial. Results for detection of gastrointestinal lesions, including polyps, ulcers, and submucosal humps from the MCE and gastroscopy were used to calculate the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy for gastric lesions. MCE detected gastric focal lesions in the entire stomach with 90.4% sensitivity, 94.7% specificity, PPV of 87.9%, NPV of 95.9% and 93.4% accuracy (Table 2). The detection of lesions was similar for MCE and gastroscopy (Table 3).

Table 2: Total Focal Lesions Detection in the Stomach (PPS)

		Gastroscopy		Total
		Positive	Negative	
MCE	Positive	94	13	107
	Negative	10	233	243
Total		104	246	350
Specificity		94.7% (91.9% - 97.5%)		
Diagnostic Accuracy		93.4% (90.8% - 96.0%)		
PPV		87.9% (81.7% - 94.0%)		
NPV		95.9% (93.4% - 98.4%)		

Table 3: Detection of Focal Lesions per Type, Location, and Size (PPS)

Lesions	Gastroscopy	MCE	Sensitivity (95%)	Specificity (95%)
	Number of patients (%)	Number of patients (%)		
Type				
Polyps	43 (12.3)	47 (13.4)	90.7 (82.0–99.4)	96.7 (94.4–98.9)
Ulcers	30 (8.6)	28 (8.0)	90.0 (73.5–97.9)	99.6 (97.6–99.9)
Submucosal humps	18 (5.1)	17 (4.9)	88.9 (65.3–98.6)	99.6 (97.6–99.9)
Others	13 (3.7)	15 (4.3)	92.3 (64.0–99.8)	98.7 (96.3–99.7)
Location				
Upper part of stomach	51 (14.5)	54 (15.4)	90.2 (82.0–98.4)	96.7 (94.4–98.9)
Lower part of stomach	53 (15.1)	53 (15.1)	90.6 (82.7–98.4)	97.9 (96.1–99.7)
Size				
<5mm	64 (18.3)	71 (20.3)	92.2 (85.6–98.8)	95.1 (92.4–97.8)
≥5mm	40 (11.4)	36 (10.3)	87.5 (77.3–97.8)	99.6 (97.6–99.9)

MCE detected 1 advanced gastric carcinoma, 2 malignant lymphomas, and 1 early stage gastric tumor. MCE did not miss any lesions of significance (including tumors or large ulcers) in comparison to conventional gastroscopy. Sensitivity was greater than or equal to 87.5% (77.3-97.8%) for lesions ≥ 5 mm. No adverse events were observed, and there were no cases of capsule retention.

CHINESE FOOD AND DRUG ADMINISTRATION (CFDA) STUDY

A second study was conducted to determine the consistency between the evaluation of the upper gastrointestinal tract by gastroscopy and CE.² The study assessed the number of detected focal upper gastrointestinal lesions and the detection rate, the consistency of the two examinations, and the visualization rate of the upper gastrointestinal tract, including the following areas:

Esophagus: dentate line

Stomach: cardia, gastric fundus, gastric body, gastric antrum, pylorus

Duodenum: duodenal bulb.

The Sponsor also evaluated the occurrence of adverse events. A total of 99 subjects were included in the study. The subjects underwent both gastroscopy and capsule endoscopy. Sensitivity was 90.9%, the specificity was 94.8%, the diagnostic accuracy was 93.9%, the positive predictive value was 83.3% and the negative predictive value was 97.3%. The number of detected focal esophageal lesions was seven and the detection rate was 7.1%. The number of detected focal duodenal lesions was eight and the detection rate was 8.1%. Effective visualization rate of the upper gastrointestinal examinations was 92% for dentate line, 97% for cardia, 95% for fundus, 99% for gastric body, 99% for gastric antrum, 99% for pylorus, and 96% for duodenal bulb. “Effective visualization rate” includes both complete and incomplete observations; only observations of “unable to be explored” are deemed as ineffective. Categorizing observations was based on the determination of the physician. While there is some lack of anatomic visualization as shown in Table 4, the device demonstrated a high NPV for clinically important lesions.

Table 4. Real-time visualization rate of the upper gastrointestinal examinations

Observations		Dentate line	Cardia	Fundus	Gastric body	Gastric antrum	Pylorus	Duodenal bulb
Real-time	C	69	80	66	78	86	88	52
	I	23	17	28	21	13	11	44
	U	7	2	5	0	0	0	3
	Effective visualization	92	97	94	99	99	99	96
	Effective visualization rate	92%	97%	94%	99%	99%	99%	96%

Note: C: "complete observation" 100% visualization of gastric mucosa, I: "incomplete observation" $\geq 70\%$ to 100% visualization of gastric mucosa, U: “Unable to be explored” $< 70\%$ visualization of gastric mucosa

No adverse events were observed and there were no cases of capsule retention.

² Zou, WB., et al., *Magnetic-controlled capsule endoscopy vs. gastroscopy for gastric diseases: a two-center self-controlled comparative trial*. Endoscopy, 2015. **47**(6): 525-528.

LITERATURE

The largest observational cohort study of screening for gastric cancer with MCE included 3182 asymptomatic Chinese individuals.³ Seven patients with ulcers and suspected malignancies were referred for gastroscopy and biopsy. The MCE studies revealed seven (0.22%) patients with advanced cancer that were all confirmed as adenocarcinoma pathologically. Additional lesions included gastric ulcers (4.9%), gastric polyps (10.4%) and submucosal tumors (3.6%). At the 2-week follow-up, capsule retention occurred in 27 cases; however, all patients excreted the capsule in the following 3 to 4 weeks.

In an additional self-controlled comparison study,⁴ ten subjects diagnosed with superficial gastric neoplasia and scheduled to undergo endoscopic submucosal dissection (ESD) at a tertiary hospital were prospectively evaluated with MCE before undergoing ESD. The diagnostic agreement of MCE, ESD and pathology were compared, including location, size and endoscopic appearance of the lesions. MCE detected 11 lesions (91.7%) in the correct location, while missing 1 neoplastic lesion at the cardia. The per-patient and per-lesion sensitivities of MCE for superficial gastric neoplasia detection were 100% and 91.7%.

There were no reports of serious adverse events in the published references.

The sponsor provided summary data to demonstrate that the NaviCam Locator is able to detect the capsule in patients. Patients were scanned with the locator a day after MCE. During the magnetic scanning, the locator was kept at a distance of within 15cm from the patient's abdomen and the scan button was pressed and held for detection. After the magnetic scanning was completed, an abdominal x-ray (patient in standing position) was carried out by another doctor. The examinations were scheduled on the 1st, 3rd, 7th and 14th day after the patient swallowed the capsule. In the study, when the capsule was still present in a patient as detected by x-ray, the locator was able to detect the presence of the capsule.

LABELING

The Sponsor provided labeling that included a user manual, patient labeling, package labels, and a promotional brochure for the NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule. The user manual addresses the known hazards and risks of the device for the intended use and incorporate safety statements to mitigate these risks. The labeling includes:

- Safety instructions intended to minimize the risk of improper use of the NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule.
- Contraindications and warnings to ensure patient and user safety in the presence of a magnetic field. This also includes an assessment form to aid users to determine if a patient has a ferromagnetic implant and should not undergo a procedure.

³ Zhao, A.J., et al., *Screening for gastric cancer with magnetically controlled capsule gastroscopy in asymptomatic individuals*. *Gastrointest Endosc*, 2018. **88**(3): p. 466-474 e1.

- The Labeling should also include the potential risk of the capsule being inadvertently aspirated during swallowing.

The patient labeling includes a summary of how the device works, how a patient should prepare for the procedure, risks associated with CE, and warnings for patients to seek medical attention, if they experience an adverse event. The patient labeling also summarizes the clinical data.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the magnetically maneuvered capsule endoscopy system and the measures necessary to mitigate these risks.

Table 5: Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measure
Infection	Reprocessing validation Sterilization validation Labeling
Adverse tissue reaction	Biocompatibility evaluation
Aspiration of capsule leading to injury	Labeling
Tissue damage	Clinical performance testing Labeling
Equipment malfunction leading to injury	Electrical, thermal, and mechanical safety testing Software validation, verification, and hazard analysis Human factors testing Non-clinical performance testing Shelf life testing Labeling
Interference with other devices (e.g., interference with image acquisition, patient information compromised, and ferromagnetic implants in users and patients)	Electromagnetic compatibility testing Software validation, verification, and hazard analysis Non-clinical performance testing Labeling
Failure to visualize areas of the stomach and duodenum leading to inadequate treatment	Clinical performance testing Non-clinical performance testing Labeling
Failure to excrete the capsule due to an obstruction resulting in abdominal pain, nausea, and vomiting	Clinical performance testing Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the magnetically maneuvered capsule endoscopy system is subject to the following special controls:

1. Clinical performance testing with the device under anticipated conditions of use must evaluate visualization of the intended region and document the adverse event profile.
2. Non-clinical testing data must demonstrate the optical, mechanical, and functional integrity of the device under physically stressed conditions. The following performance characteristics must be tested, and detailed protocols must be provided for each test:
 - i. A bite test must be performed to ensure that the capsule can withstand extreme cases of biting.
 - ii. A pH resistance test must be performed to evaluate integrity of the capsule when exposed to a physiological relevant range of pH values.
 - iii. A battery life test must be performed to demonstrate that the capsule's operating time is not constrained by the battery capacity.
 - iv. A shelf life test must be performed to demonstrate that the device performs as intended at the proposed shelf life date.
 - v. Optical testing must be performed to evaluate fundamental image quality characteristics such as resolution, field of view, depth of field, geometric distortion, signal to noise ratio, dynamic range, and image intensity uniformity.
 - vi. A color performance test must be performed to compare the color differences between the input scene and output image.
 - vii. A photobiological safety analysis must be performed based on maximum (worst-case) light exposure to internal gastrointestinal mucosa, and covering ultraviolet, visible and near-infrared ranges, as appropriate. A mitigation analysis must be provided.
 - viii. Performance testing must demonstrate that the viewing software clearly presents the current frame rate, which is either adjustable manually by the user or automatically by the device. Testing must demonstrate that the viewing software alerts the user when the video quality is reduced from nominal due to imaging data communication or computation problems.
 - ix. A data transmission test must be performed to verify the robustness of the data transmission between the capsule and the receiver. This test must include controlled signal attenuation for simulating a non-ideal environment.
 - x. Magnetic field strength testing characterization must be performed to identify the distances from the magnet that are safe for patients and users with ferromagnetic implants, devices, or objects.
3. Software validation, verification, and hazard analysis must be provided.
4. Electrical safety, thermal safety, mechanical safety, and electromagnetic compatibility (EMC) testing must be performed.
5. The patient-contacting components of the device must be demonstrated to be biocompatible.
6. Performance data must validate the reprocessing instructions for the reusable components of the device.

7. Performance data must demonstrate the sterility of any device components labeled sterile.
8. Human factors testing must demonstrate that the intended users can safely and correctly use the device, based solely on reading the instructions for use.
9. Clinician labeling must include:
 - i. Specific instructions and the clinical and technical expertise needed for the safe use of the device;
 - ii. A detailed summary of the clinical testing pertinent to use of the device, including information on effectiveness and device- and procedure-related complications;
 - iii. The patient preparation procedure;
 - iv. A detailed summary of the device technical parameters;
 - v. Magnetic field safe zones;
 - vi. A screening checklist to ensure that all patients and operating staff are screened from bringing ferromagnetic implants, devices, or objects near the external magnet;
 - vii. Reprocessing instructions for reusable components;
 - viii. Shelf life for single use components; and
 - ix. Use life for reusable components.
10. Patient labeling must include:
 - i. An explanation of the device and the mechanism of operation;
 - ii. The patient preparation procedure;
 - iii. A brief summary of the clinical study; and
 - iv. A summary of the device- and procedure-related complications pertinent to use of the device.

BENEFIT/RISK DETERMINATION

The risks include adverse tissue reaction, damage to the intestinal tract or abdominal cavity, equipment malfunction leading to injury, electromagnetic field incompatibility or interference, poor image acquisitions, misinterpretation of the captured images and failure to excrete the capsule. Most of the identified risks have been assessed via pre-clinical testing such as biocompatibility testing, EMC, and electrical safety testing (see above). Risks associated with clinical outcomes such as misinterpretation of results and failure to excrete the capsule were evaluated in the two clinical studies as well as in numerous clinical studies performed with the device and reported in literature. The available clinical data as well as accumulated experience using the device in the European Union and China demonstrate that the NaviCam systematically produces results comparable to “gold standard” (gastroscopy/EGD procedures) and that no serious adverse events have been reported associated with failure to excrete the capsule.

The benefit of the NaviCam Endoscopy System is to provide noninvasive visualization of the stomach. Also, the rate of adverse events associated with the NaviCam is extremely low, with the majority of complaints associated with the procedure preparation process rather than with the capsule procedure itself. Among the 11 studies using the device, there are a few, which

specifically evaluate the use of the device for identification of pathologic lesions. The assurance of a true negative finding is an important metric of effectiveness and the NPV demonstrated in the clinical studies to support MCE was greater than 95%. In addition, MCE did not miss any clinically significant lesions. However, because there is still a possibility of missing a clinically significant lesion, a warning was added to the labeling that a normal or negative study does not eliminate the possibility of the missing a significant lesion.

Based on the study with 350 patients with upper GI symptoms who underwent both MCE and upper endoscopy the sensitivity and NPV for detecting the same abnormality 90.2% and 95.9%, respectively. An additional benefit is the potential to avoid the need for sedation and an endoscopic examination. The risks of the NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule are the potential for a small bowel obstruction in patients that are predisposed to small bowel obstruction and the possible failure to visualize significant gastric lesions. Based on these known benefits and primarily potential risks the benefits of the device as a tool to visualize the stomach outweigh the risks.

Patient Perspectives

Risk tolerance varies amongst patients and affects individual patient decisions as to whether risks are acceptable in exchange for a probable benefit. In the clinical study conducted on 350 patients, a patient acceptance evaluation was performed. This evaluation revealed that from the 350 patients who have completed the two examinations, 335 (95.7%) preferred the NaviCam over traditional gastroscopy. Only 4 (1.1%) preferred traditional gastroscopy and 11 (3.1%) had no inclination. The low risk nature of the device, the patient acceptance results, and the opportunity to avoid sedation, has been shown to result in a positive patient perspective with preference for the minimally invasive and well tolerated procedure of the NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule as compared to upper endoscopy with sedation.

Benefit/Risk Conclusion

In conclusion, given the available information above, the data support that for the indications for use stated above, the probable benefits outweigh the probable risks for the NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule. The device provides benefits and the risks can be mitigated using general controls and the identified special controls.

CONCLUSION

The De Novo request for the NaviCam Capsule Endoscopy System with NaviCam Stomach Capsule is granted and the device is classified under the following:

Product Code: QKZ

Device Type: Magnetically maneuvered capsule endoscopy system

Class: II

Regulation: 21 CFR 876.1310