DE NOVO CLASSIFICATION REQUEST FOR ACCUMEASURE™ SYSTEM

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Endoscopic light-projecting measuring device. An endoscopic light-projecting measuring device projects light on a mucosal surface and uses software to determine the dimensions of observable features of interest.

NEW REGULATION NUMBER: 21 CFR 876.1530

CLASSIFICATION: Class II

PRODUCT CODE: QTH

BACKGROUND

DEVICE NAME: AccuMeasure™ System

SUBMISSION NUMBER: DEN210032

DATE DE NOVO RECEIVED: August 9, 2021

SPONSOR INFORMATION:

VTM Technologies Ltd.
65 Derech HaAtzmaut
Haifa, Israel 3303333

INDICATIONS FOR USE

The AccuMeasure™ System is intended to be used as an accessory in conjunction with an endoscope to measure observable anatomy and pathology in the gastrointestinal tract. The AccuMeasure™ System provides no therapeutic or diagnostic function.

LIMITATIONS

The sale, distribution, and use of the AccuMeasure™ System are restricted to prescription use in accordance with 21 CFR 801.109.

The device is not intended to be used as a stand-alone diagnostic device.

In the clinical study for the AccuMeasure™ System, the usability and safety of the device was assessed while measuring the diameter of colon polyps in patients undergoing routine colonoscopy. Due to limitations in determining the true length of structures in

vivo, the clinical study did not assess the accuracy of the device. Clinicians provided subjective assessments regarding the use of the device including ease of use and duration of use.

The device is compatible with forward viewing gastrointestinal endoscopes with working channels ≥ 3.2 mm.

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

DEVICE DESCRIPTION

The device is used in conjunction with an endoscope to measure objects on the mucosal surface of the gastrointestinal (GI) tract. The device consists of two components (1) the measuring device and (2) a processing unit. See image of the device in figure 1 below.

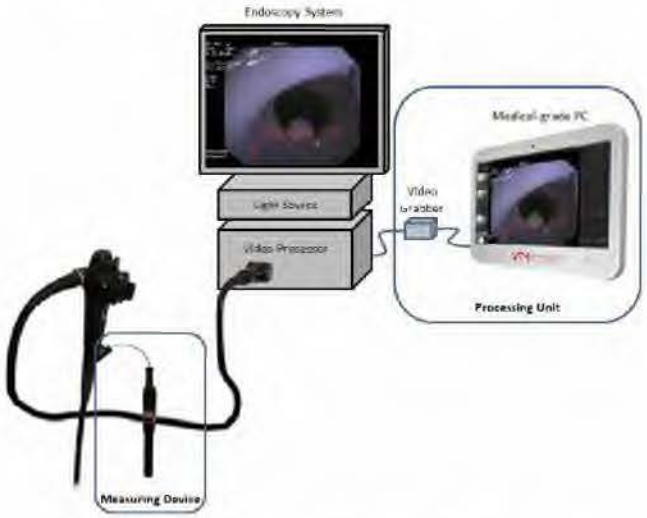

Figure 1. The AccuMeasure™ System

The measuring device consists of a through the scope probe that is connected to a handheld laser source. During use, the distal end of the probe extends beyond the end of the endoscope working channel and is positioned to project a red line across the object to be measured. The laser source attaches to the probe via a magnetic connection. The magnetic sensor allows for laser emission only when the probe is connected. The probe is reusable and waterproof. See image of the measuring device in figure 2 below.

Figure 2. Measuring device

The processing unit includes a video grabber and a touch screen PC. The medical-grade PC comes with dedicated software for conducting measurements during an endoscopic procedure. The video grabber is an off-the-shelf video grabber model AV.io HD by Epiphan Video. The video grabber is connected to the endoscope video processor video output port, captures the video from the endoscope, and inputs it to a medical grade PC via a standard USB port. The provided medical-grade PC is an off-the shelf component connected with the endoscopic system through the video grabber. The PC has a 22-inch touchscreen with a high-end graphics processing unit and runs Windows 10 64 bit.

The AccuMeasure™ System software allows users to interact with the captured endoscopic images and obtain measurements. The software performs the calculation and provides a measurement of distance using the ruler function or displays a trace between two selected points on the laser line. The software enables recording of sessions for conducting measurements during an endoscopic procedure. The software is pre-calibrated for each endoscope model to find its camera parameters and distortion coefficients. It removes the fisheye and additional artifacts.

Principle of operation

Prior to the clinical procedure, the endoscope is checked to make sure it is known to the AccuMeasure™ System by taking a validation image with the endoscope. During the clinical procedure, when the physician wants to make a measurement, the AccuMeasure™ probe is inserted through the instrument channel until the probe tip is seen at the distal end of the endoscope. The physician then attaches the laser source to the proximal end of the AccuMeasure™ probe handle. The laser source is turned on and the laser line is projected over the structure to be measured. The physician can acquire the image using the endoscope's 'Freeze' button or the AccuMeasure™ software's 'Capture' button. The unique identification marking on tip of the probe must be clearly visible in the image. If the identification marking on the tip is not clearly visible, the measurement function will be disabled for that image. If the image is acquired correctly, the triangle overlay can be seen over the image and measurements can be made by dragging the target markers to the edges of the structure to be measured. The AccuMeasure™ software calculates the positioning of the distal tip in 3 dimensions (3D) relative to the endoscope camera, and hence the positioning of the laser plane. Using the triangulation principle, every point along the laser line designated by the operator has 3D coordinates. Several measurements may be taken per image. See image of the measuring sequence in figure 3 below.

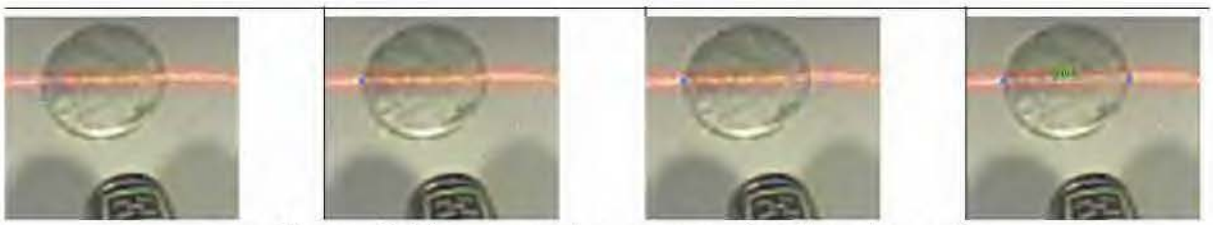

Figure 3. Measurement sequence using the ruler mode

SUMMARY OF NONCLINICAL/BENCH STUDIES

Non-clinical studies conducted for the AccuMeasure™ System are summarized below.

BIOCOMPATIBILITY

The AccuMeasure™ probe is classified as mucosal membrane contacting for limited duration (≤ 24 hours). The AccuMeasure™ processing unit is not patient contacting.

To support biocompatibility, appropriate biocompatibility assessments in accordance with ISO 10993-1, 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" were provided following simulated reprocessing cycles. The following tests were performed on the AccuMeasure™ probe:

1. Cytotoxicity
2. Sensitization
3. Irritation

Results assessed by FDA support the biocompatibility of the AccuMeasure™ probe.

REPROCESSING/CLEANING

The AccuMeasure™ System is provided non-sterile and multi patient use. The AccuMeasure™ System is reprocessed before the first use and following each clinical use. The reprocessing instructions for the measuring device were validated per FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling dated March 17, 2015.The reprocessing validation included manual cleaning and high-level disinfection for the probe and low-level disinfection for the non-patient contacting laser source.

ELECTROMAGNETIC COMPATIBILITY & ELECTROMAGNETIC SAFETY

The electrical and electromagnetic safety for the AccuMeasure™ System were assessed per ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) (19-4) and IEC 60601-1-2 Edition 4.0 2014-02 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

SOFTWARE

The software was reviewed according to the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005. Appropriate software documentation consistent with a "Moderate" level of software concern were provided.

Cybersecurity was reviewed according to FDA guidance document "Content of Premarket Submission for Management of Cybersecurity in Medical Devices" dated October 2, 2014.

PERFORMANCE TESTING - BENCH

The integrity and performance of the AccuMeasure™ System was evaluated with the non-clinical bench testing summarized in Table 1.

Table 1. Summary of non-clinical bench testing for the AccuMeasure™ System

Test	Purpose	Method	Acceptance Criteria	Results
Accuracy Validation	The test was to demonstrate the accuracy of the device.	To simulate the physiological conditions in colonoscopy, phantoms were constructed. The phantoms contained simulated round and flat polyps. Simulated polyps were between 5- 15 mm in diameter. The probe was inserted through the working channel of a colonoscope for imaging. The software was used to acquire images of polyps at various distances and angles using the phantoms.	Relating to specific object sizes, the required measurement accuracy is: Object ≤ 5 mm: +/- 0.5 mm; Object >5 mm - 10mm: -0.5 mm - +10% (e.g., for 10 mm, 9.5 mm – 11.0 mm); and Object >10 mm: -5% - +10% (e.g., for 15 mm, 14.2 mm – 16.5 mm)	The device was able to meet the acceptance criteria for measuring the diameter of the simulated round and flat polyps for all sizes.
Laser Safety Testing	Tests were conducted to demonstrate the safety of the laser source.	The AccuMeasure™ laser system was tested for eye safety and tissue/skin safety according to IEC 60825-1.	The AccuMeasure™ laser system should meet Accessible Emission Limit (AEL) for classifying it as Class II and MPE for skin safety for duration of exposure above 10 seconds.	The laser source met the requirements per IEC 60825-1.
Laser Bend Loss	The test was to quantify any loss of laser power	The power was measured while the	The power output measurements of	Power measurements for

	as a result of bending the probe. This is important because the working channel of the endoscope is intended to bend as it is positioned in the GI tract. Therefore, the optical fiber of the device will need to bend without losing power.	AccuMeasure™ probe was straight, and this measurement was used as a reference. The AccuMeasure™ probe was then put in a curved position with (b)(4) full turns (b)(4) (b)(4) in diameter and (b)(4) full turn of (b)(4) (b)(4), which was the minimum curvature of the colonoscope. The power measurements of the probes were taken in the curved position. Finally, the probes were straightened again, and the power was measured.	straight and bent probes should be similar with no significant change with less than (b)(4) reduction for the bent configuration between measurements for the same probe	the bent probes were within (b)(4) of the straight probes.
Pushability	Endoscopic tools are manually advanced in the working channel of an endoscope in small segments. If the tool is flexible these segments are shorter, as the tool tends to bend more easily, increasing the number of strokes and making the tool less usable.	The number of the strokes it takes to advance the probe fully through the working channel were compared to that of forceps and snares. 1. Forceps were inserted until its tip extended from the distal end of the working channel and the number of strokes were documented. 2. Repeat step 1 with snare. 3. Repeat step 1 with AccuMeasure Probe. 4. Repeat steps 1-3 with endoscope rolled in a (b)(4) diameter	The average number of strokes required to fully insert the AccuMeasure™ probe shall be comparable to the forceps and snares tools. It should be less than (b)(4) higher than that of the tool with the highest number of strokes.	The number of strokes was similar for the snare, forceps, and the AccuMeasure™ probe.
Pressure by Probe Tip	This test compares the pressure applied to plastic material by the probe tip to that of forceps and snare to	Probe initially inserted through the holding plastic jig and extends (b)(4) from jig end,	The force required to perforate the plastic by the probe must not be less than the minimum of open or closed	The recorded forces indicate that the pressure applied by the probe tip is greater than that of a closed snare and an

	evaluate the chances of perforation.	probe's tip pushed against the plastic until the probe tip perforates the plastic. The required force applied was documented. The test was repeated with forceps and snares in the open and closed configurations.	forceps and open or closed snare.	open forceps. The probe does not increase the chances for perforation, since the forces exerted by the probe's tip are comparable to existing tools.
Battery Life	This test was performed to determine battery lifetime for the laser source, and to verify the action of the 'weak battery' indicator light embedded it its switch	The laser source was connected to the probe and continuously run, snapshots of the laser line and battery indicator were taken every minute until the laser line faded out. Transition time of the indicator light from green to red was also monitored.	Batteries should last at least 5 hours. Laser Source "near-empty" battery indicator shall allow at least half an hour of remaining operation on batteries once it has changed color from green to red/orange.	The batteries lasted for at least 5 hours of continuous operation before providing "near-empty" battery Indication. Then with the "near empty indication the emission lasted for an additional (b)(4) (b)(4) in all cases.
Probe Durability to Reprocessing Cycles	The test was conducted to simulate the worst-case simulated exposure to detergent and disinfectant and determine that the probe is still functional after 500 simulated use cycles.	For the cleaning, the probe was soaked in Endozime Premuim APA for (b)(4) and (b)(4) in (b)(4) times concentrated as compared to Endozime's IFU maximal concertation recommendation. After soaking, the probes were removed and soaked in a container with (b) (b)(4) of tap water for (b)(4) . The probes were rinsed under tap water and dried. Following rinsing, the probes were visually inspected for integrity, laser line emission was verified, and water resistance was verified.	For visual inspection, there should be no defects at the handle or distal end and the adhesion between the PTFE sheath and the probe handle should be intact. For laser line integrity, the laser line should turn on and the line should be clean and straight. For water resistance, the probe should be water resistant to ensure the mechanical integrity of the probe.	All probes remained intact, laser lines were visible, and probes were still water resistant.

		For the High-Level Disinfection (HLD), the probes were soaked for (b) hours in Cidex OPA Solution in the Minimum Effective Concentration (MEC). Following HLD, the probes were rinsed with tap water according to Cidex's IFU and device's IFU. The same assessments were conducted to determine the integrity of the probe.		
Laser Marking Integrity	Demonstrate that the unique identifier at the tip of the probe remains intact after reprocessing cycles.	The ID pattern was captured and visually inspected. The probes underwent (b)(4) cycles of enzymatic cleaning and HLD. At the end of the process each one of the probes was placed into the tip holder jig and the ID pattern was captured and visually inspected.	ID pattern integrity at the probe distal tip should remain intact.	The unique ID pattern remained intact for all probes and were recognized by the system following reprocessing.
Probe Water Resistance	This test was performed to evaluate the water resistance of the probe.	The probe sealing cap was removed and (b)(4) pieces of humidity detection strips were carefully inserted. One piece into the probe connector the other piece into the probe sealing cap. The probes caps were firmly placed on the probe handles. The probes were immersed in a water pillar (b)(4) diameter and (b)(4) length, filled with tap water, making sure both distal and	For water resistance, the humidity detection strips should be blue. No visible fluid residue inside PTFE sheath, indicating the adhesion region between the PTFE sheath and the probe handle is intact. Laser line emission was used to verify integrity of optical connector.	The humidity strips remained blue for all probes exposed to water. Also, the probes were able to emit a laser line following exposure to water. All probes were water resistant.

		proximal ends of the probe are below 1 meter of water. The test was performed for 30 minutes. The probes were taken out from the water, wiped and dried. The probes caps were removed, humidity detection strips were carefully removed and checked. In case of humidity exposure, the strips will change the color from blue to pink.		
Torque Durability	The test was to verify mechanical integrity of the stainless-steel coil that composes the body of the probe the PTFE sheath and the strain point of adhesion between the PTFE and probe handle during probe rotation.	The probe handle was connected via an adapter to a stepper motor while the distal end of the probe is fixed in a collet, the distance between the collet and the handle is (b)(4) (b)(4). The stepper motor controller script was as follows: (b)(4) turn CCW, (b)(4) sec wait, (b)(4) turn CW, (b)(4) sec wait Duration @ (b)(4) RPM: (b)(4) sec / cycle Total duration for (b)(4) cycles: (b)(4) minutes.	Laser line should be visible and straight. The adhesion region between the PTFE sheath and the probe handle was visibly inspected and should be intact. Also, the probe should be water resistant.	The laser lines were all visible and straight. Also, there was no damage to the adhesion region between the PTFE sheath and the probe handle.
Tension-Compression Fatigue	The probe is inserted through the working channel of a curved endoscope and is required to rotate around its axis. As a result, tension and compression occurs. This test was to simulate tension/compression fatigue that exceed the expected cycles during the lifetime of the probe.	The probe was placed in a vise. The handle was connected to the stepper motor via an adaptor. The vise and the motor were positioned on the same plane and the probe is rotated CW and then CCW for a total of (b)(4) revolutions at (b)(4) RPM (duration is approximately 1	The devices were checked for laser line emission, visually inspected under a microscope (adhesion region between the PTFE sheath and the probe handle, PTFE integrity at the point of fatigue, and water resistance was confirmed.	The laser lines were all visible and straight. Also, there was no damage to the adhesion region between the PTFE sheath and the probe handle.

		hour and 15 minutes).		
Probe drop test	This test is intended to examine the robustness of probe construction and its resistance to accidental drops.	The probe was held in one hand at height of (b)(4) and dropped on a PVC floor (b)(4) times. After each drop, the laser line integrity was verified.	Laser line emission should remain intact and the probe should be water resistant.	The probes projected a straight line, and the probes were still water resistant following the test.
Probe and Laser Source Connector Reliability	The probe and laser source are routinely connected and disconnected. The connection between them is secured by two ring magnets, one at the probe handle and the other at the laser source. This test is to verify the reliability of the connection.	(b)(4) cycles of connection and disconnection of the probe from the laser source were performed manually. Repeat the previous step with another laser source, conducting (b)(4) connect-disconnect cycles with each probe, for a total of (b)(4) cycles per laser source.	Laser source connector shall withstand (b)(4) connection/disconnection cycles - Visual inspection - Direct power output shall not reduce below (b)(4) at the end of the cycles Probe connector shall withstand (b)(4) connection/ disconnection cycles. - Visual inspection - The probe shall produce no less than (b)(4) when connected to the same laser source at the end of their cycles	The probe/laser-source connector reliability was demonstrated to withstand (b)(4) cycles per probe and (b)(4) cycles per laser source.

SUMMARY OF CLINICAL INFORMATION

Study Overview

The sponsor conducted a clinical study that included (b)(4) patients who were undergoing routine colonoscopy procedures at a healthcare facility in Israel. All patients were adults ages 20 to 75. During procedures where polyps were detected, the AccuMeasure™ System was used to obtain measurements. The physicians also made qualitative assessments based on the use of the device. There were (b)(4) physicians that participated in the study. The colonoscopes used in the study were (b)(4) endoscopy system, (b)(4) (b)(4) colonoscopes, and (b)(4) colonoscopes. Each colonoscope was calibrated to the system. The purpose of the study was to determine the safety and usability of the AccuMeasure™ System.

The following data was collected during the study:

- AccuMeasure™ session data that included still images and measurement results. Each measurable image contained the tip of the probe used, with a unique identification marker. Patient data was not included in the saved session.
- Specific colonoscope used including the model and serial number
- User experience with the device
- Adverse event monitoring

Study Endpoints

- Adverse events (both AE and SAE) were analyzed at the end of the study. The AccuMeasure™ System was defined as safe only if no damage caused to the patient was found to be as a result of using the AccuMeasure™ System.
- User experience was defined as positive if the average value obtained from the user's answers to the usability questionnaire was (b)(4) The scale was 1 to 5 for the questionnaire, 1 is very poor; 2 is poor; 3 is satisfactory; 4 is good; and 5 is excellent.

Results

Of the (b)(patients that were enrolled in the study, (patients were excluded due to poor preparation, (b)(4 patients had no polyps detected during the procedure, and (b) patients were excluded due to an issue with the endoscope that was unrelated to the AccuMeasure™ System. The remaining (b)(4 patients had at least (b)(4) or more polyps detected. The physicians attempted to measure a total of (b)(polyps in these (b)(patients. (b)(4) of the (b)(polyps could not be measured due the following reasons: polyps were in regions of suboptimal preparation, cases of partial visibility of the polyp, or exaggerated peristalsis. Therefore, there were (b)(polyps remaining that could be measured. Of these (b)(polyps, the physicians measured (b)(polyps. The remaining (b)(polyps that were not measured in the study were due to device-related errors for (b) polyps and an endoscope related error for (b)(4) polyp.

The results presented in Figure 4 show the score that was obtained by the participating physicians regarding their subjective assessment to different aspects of device manipulation.

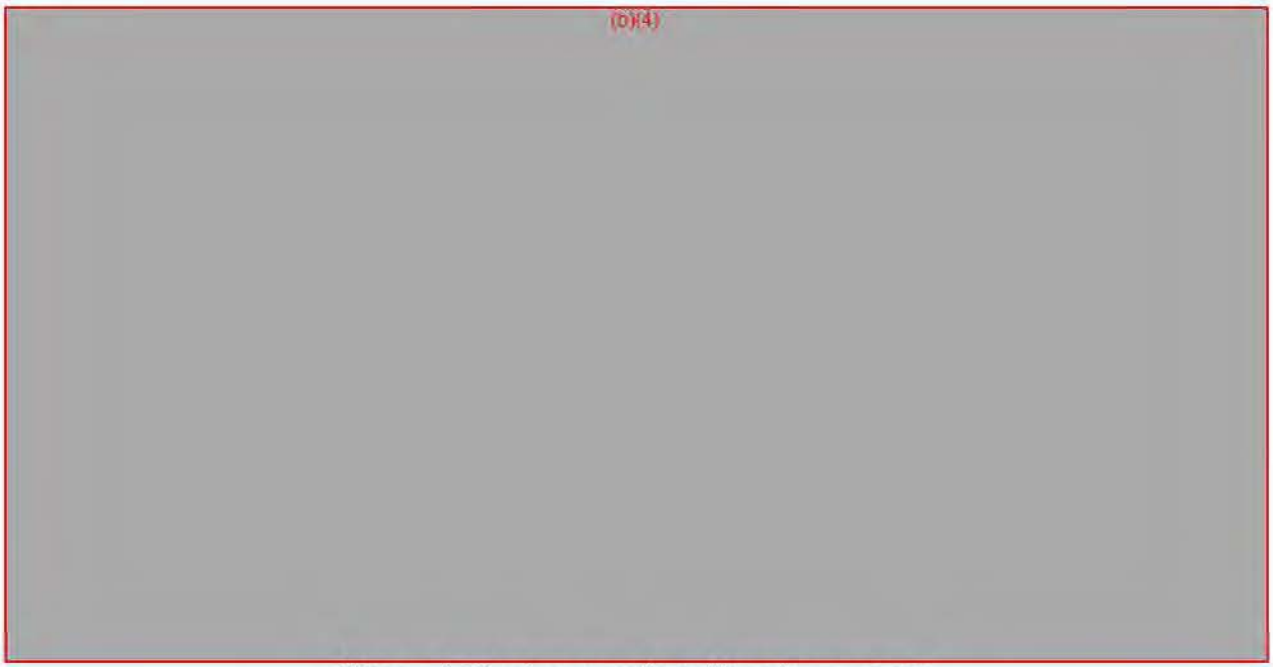

Figure 4. Device operation- User Assessment

The results presented in Figure 5 show the score that was obtain by the participating physicians regarding their agreement with each of the provided statements.

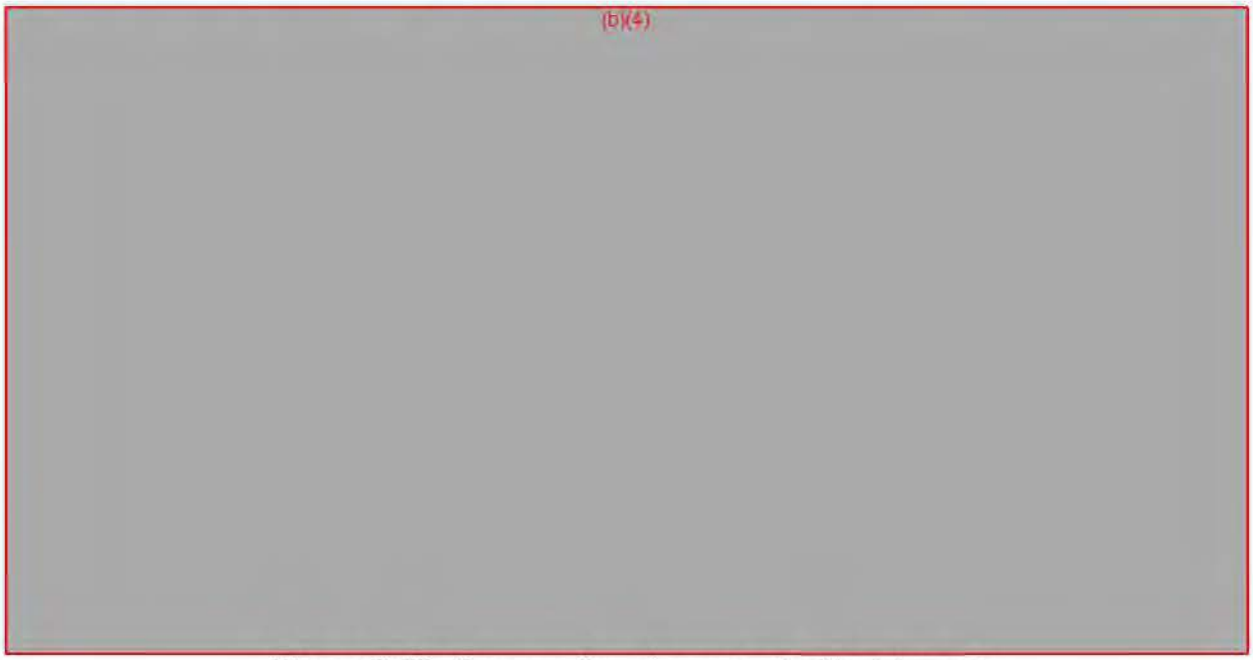

Figure 5. Device operation- Agreement with statements

The assessment included questions about pushability, manually advancing the device through the working channel of the endoscope, maneuverability of the probe, use of the software and the touchscreen, and clarity of the laser line. The mean score was (b)(4) for all questions except for

the time to obtain a measurable image (mean score was (b)(4)). Physicians felt that it took a longer time to obtain an image that could be used for making measurements.

Adverse Events
There were no adverse events associated with using the AccuMeasure™ System during the (b)(4) procedures where polyps were detected.

Summary
In summary, the study supporting the AccuMeasure™ System demonstrated that the device was safe for use and able to make measurements under conditions where clear images can be obtained.

Pediatric Extrapolation
In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The Sponsor provided labeling that included a user manual for the AccuMeasure™ System. The user manual addresses the known hazards and risks of the device for the intended use and incorporates safety statements to mitigate these risks. The labeling includes:

- Instructions intended to minimize the risk of improper use of the AccuMeasure™ System including a summary of how to navigate the software.
- The AccuMeasure™ System is compatible with commercially available flexible colonoscopes and gastroscopes having working channels of ≥ 3.2 mm in diameter, and both Standard-Definition and High-Definition endoscopy systems are supported. A specific warning indicates potential damage to endoscopes with narrower working channels.
- The user manual includes the accuracy of the device and states that the accuracy was determined using bench testing.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the endoscopic light-projecting measuring device, and the measures necessary to mitigate these risks.

Identified Risks to Health	Mitigation Measures
Ineffective treatment due to the device providing inaccurate measurements	Non-clinical performance testing Labeling
Device failure/malfunction leading to injury	Non-clinical performance testing Electrical, thermal, and mechanical safety testing Software validation, verification, and hazard analysis

Identified Risks to Health	Mitigation Measures
	Labeling
Device failure due to interference with other devices	Electromagnetic compatibility testing
Adverse tissue reaction	Biocompatibility evaluation
Extended procedure time leading to increased adverse events	*In vivo* performance testing
Infection	Reprocessing validation Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the endoscopic light-projecting measuring device is subject to the following special controls:

(1) *In vivo* performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must evaluate:
   (i) Visualization during the procedure;
   (ii) Ease of procedure as reported by the intended user; and
   (iii) User acceptability of imaging time.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
   (i) Accuracy validation;
   (ii) Endoscope compatibility testing;
   (iii) Battery life testing;
   (iv) Durability testing; and
   (v) Light safety testing.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Electrical, thermal, and mechanical safety testing must be performed.

(6) Performance testing must demonstrate electromagnetic compatibility (EMC) of the device in the intended use environment.

(7) Methods and instructions for reprocessing reusable components must be validated.

(8) Labeling must include:
   (i) Device technical parameters, including a description of the accuracy of the device;
   (ii) Information regarding endoscope compatibility;

(iii) Warning for light hazards and protection for patient and operator; and
(iv) Validated reprocessing instructions.

BENEFIT-RISK DETERMINATION

The risks of the device are based on nonclinical laboratory testing as well as data collected in a clinical study described above.

During the clinical study, there were no device related adverse events. However, in the user questionnaire, physicians felt it took more time to obtain a usable image for making measurements. The additional time that it takes to obtain a usable image in the device can prolong the procedure time and put patients at risk for adverse events. Also, if a clear image cannot be taken due to movement in the GI tract, poor bowel preparation, or exaggerated peristalsis the device cannot be utilized.

The probable benefits of the device are based on nonclinical laboratory data.

The AccuMeasure™ System provides accurate measurements of round and flat structures when images are taken from a variety of angles and distances between the distal end of the probe and the structure. The AccuMeasure™ System demonstrated greater accuracy than other methods of assessing length during endoscopy procedures (e.g., visual estimation, biopsy forceps, and snares). Also, these other endoscopy tools are not intended for measurement. The assessment of polyp size is important for determining which polyps are removed and the follow up care for patients. Larger polyps tend to have more advanced histological features. Therefore, polyps ≥ 10 mm are typically removed during colonoscopy. Most endoscopists measure polyp size by visualization or they may use an endoscope tool like a snare or biopsy forceps that are available during the procedure. In a study comparing the accuracy of measurements made with biopsy forceps and by visual estimation[1], the error range for visual estimation was greater than (b)(4) for polyps 6-9 mm and greater than (b)(4) for polyps ≥ 10 mm. Similar error ranges were found using biopsy forceps. The bench testing demonstrated that the accuracy of the AccuMeasure™ System according to the polyp size was significantly greater than that of the visual estimation and forceps (polyps > 5 mm- 10 mm the accuracy is -0.5 mm – 10% (e.g., for 10 mm, 9.5 mm – 11.0 mm). The bench testing results indicate that the method using the AccuMeasure™ System can increase the accuracy of polyp size measurement regardless of polyp size, compared to previously published estimates of polyp size using visual estimation or endoscopic accessories like biopsy forceps.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

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[1] Kim JH, Park SJ, Lee JH, Kim TO, Kim HJ, Kim HW, Lee SH, Baek DH, Bigs BU. Is forceps more useful than visualization for measurement of colon polyp size? World J Gastroenterol. 2016 Mar 21;22(11):3220-6. doi: 10.3748/wjg.v22.i11.3220. PMID: 27003999; PMCID: PMC4789997.

In conclusion, given the available information above, for the following indication statement:

> The AccuMeasure™ System is intended to be used as an accessory in conjunction with an endoscope to measure observable anatomy and pathology in the gastrointestinal tract. The AccuMeasure™ System provides no therapeutic or diagnostic function.

The probable benefits outweigh the probable risks for the AccuMeasure™ System. The device provides benefits, and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the AccuMeasure™ System is granted and the device is classified as follows:

> Product Code: QTH
> Device Type: Endoscopic light-projecting measuring device
> Regulation Number: 21 CFR 876.1530
> Class: II