July 26, 2022

RQMIS Inc.
Barry Sands
President and Founder
110 Haverhill Road
Suite 524
Amesbury, MA 01913

Re: DEN210032
Trade/Device Name: AccuMeasure™ System
Regulation Number: 21 CFR 876.1530
Regulation Name: Endoscopic light-projecting measuring device
Regulatory Class: Class II
Product Code: QTH
Dated: August 6, 2021
Received: August 9, 2021

Dear Barry Sands:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the AccuMeasure™ System, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the AccuMeasure™ System, and substantially equivalent devices of this generic type, into Class II under the generic name endoscopic light-projecting measuring device.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously

classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On August 9, 2021, FDA received your De Novo requesting classification of the AccuMeasure™ System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the AccuMeasure™ System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the AccuMeasure™ System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

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 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

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.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the endoscopic light-projecting measuring device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food

and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Stephanie Cole at 301-796-8587.

Sincerely,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
OHT3: Office of GastroRenal, ObGyn,
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Center for Devices and Radiological Health