UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 11, 2019

MOTUS GI HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38389**	**81-4042793**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification No.)*

1301 East Broward Boulevard, 3rd Floor Ft. Lauderdale, FL	**33301**
(Address of principal executive offices)	*(Zip Code)*

Registrant's telephone number, including area code: **(954) 541-8000**

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchanged on Which Registered**
Common Stock, $0.0001 par value per share	MOTS	The Nasdaq Capital Market

Item 7.01. Regulation FD Disclosure.

On June 11, 2019, Motus GI Holdings, Inc. (the "Company") issued a press release announcing that the Company's 510(k) premarket notification for the second-generation of the Pure-Vu System has been reviewed and cleared by the U.S. Food and Drug Administration. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01. Other Events

On June 11, 2019, the Company announced that its 510(k) premarket notification for the second-generation of the Pure-Vu System ("Pure-Vu GEN2") has been reviewed and cleared by the U.S. Food and Drug Administration.

The Pure-Vu GEN2 is designed to improve the mobility, setup logistics of the system and enhance navigation through the colon, while retaining all the same cleansing functionality as the current generation of the Pure-Vu System. The Pure-Vu GEN2 Workstation has a reduced footprint and is mounted on a roll stand, allowing for the Pure-Vu GEN2 to be moved to different procedure rooms or other areas of the facility as needed. The Pure-Vu GEN2 also has improvements that reduce the number of steps to set up the system and simplifies the loading process onto the colonoscope.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibit is furnished with this report:

Exhibit No.	Description
99.1	Press Release issued by Motus GI Holding, Inc. June 11, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MOTUS GI HOLDINGS, INC.

Dated: June 11, 2019

By: */s/ Timothy P. Moran*
Name: Timothy P. Moran
Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Motus GI Holding, Inc. June 11, 2019

Exhibit 99.1

Motus GI Receives FDA Clearance to Market Pure-Vu® GEN2

– FDA clearance marks key regulatory milestone and advances commercial strategy for launch in U.S. hospital market in 2019 –

FORT LAUDERDALE, FL, June 11, 2019 – Motus GI Holdings, Inc., (NASDAQ: MOTS) ("Motus GI" or the "Company"), a medical technology company dedicated to improving clinical outcomes and enhancing the cost-efficiency of colonoscopy, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for the second-generation Pure-Vu® System ("Pure-Vu® GEN2") to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure.

"Inadequate bowel preparation prior to colonoscopy remains an unmet need that affects a significant percentage of patients' ability to receive a complete and high-quality exam. This often leads to canceled, delayed and aborted procedures, resulting in prolonged hospitalizations and increased costs for both patients and providers," commented Jason B. Samarasena, MD FACG, Associate Clinical Professor of Medicine, Division of Gastroenterology School of Medicine, University of California Irvine. "The Pure-Vu® System provides an important solution to address the significant clinical challenges and inefficiencies associated with inadequate prep and the Pure-Vu® GEN2 provides an innovative, easy to use platform that enables a streamlined approach to the overall procedure."

The Pure-Vu® System is a U.S. FDA-cleared medical device indicated to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure. The device integrates with standard and slim colonoscopes to enable safe and rapid cleansing during the procedure while preserving established procedural workflow and techniques. Pure-Vu® GEN2 has been designed to improve the mobility, setup logistics of the system and enhance navigation through the colon, while retaining all the same cleansing functionality as the first generation of the Pure-Vu® System.

Pure-Vu® GEN2 System

"Receiving FDA clearance for our Pure-Vu® GEN2 represents a major milestone for the Company. The Pure-Vu® System continues to demonstrate outstanding cleansing performance in poorly prepped colons, including the statistically significant improvement in colon cleanliness in hospitalized patients as recently demonstrated by the positive outcome of our REDUCE study. With our robust portfolio of health economic and clinical data coupled with 510(k) clearance from the FDA of Pure-Vu® GEN2, we are now well positioned to execute our planned commercial launch of the Pure-Vu® System this year and advance toward our goal of establishing the Pure-Vu® System as a new standard of care in key endoscopy segments," commented Tim Moran, Chief Executive Officer of Motus GI.

Our planned initial launch will focus on the inpatient colonoscopy market where challenges with insufficient bowel prep slow diagnosis, diminish the quality of care, and add significant costs to hospital systems. Motus GI believes that the Pure-Vu® System may improve quality of care and potentially reduce healthcare costs by reliably and predictably moving patients through the hospital system to a successful examination.

About Motus GI and the Pure-Vu® System

Motus GI Holdings, Inc. is a medical technology company, with subsidiaries in the U.S. and Israel, dedicated to improving clinical outcomes and enhancing the cost-efficiency of colonoscopy. The Company's flagship product is the Pure-Vu® System, a U.S. FDA cleared medical device indicated to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure. The device integrates with standard and slim colonoscopes to enable safe and rapid cleansing during the procedure while preserving established procedural workflow and techniques. The Pure-Vu® System has received CE mark approval in Europe. The Pure-Vu® System is currently being introduced on a pilot basis in the U.S. market, and the Company is planning to initiate a commercial launch focused on the U.S. hospital market in 2019. Challenges with bowel preparation for inpatient colonoscopy represent a significant area of unmet need that directly affects clinical outcomes and increases the cost of care in a market segment that comprises approximately 1.5 million annual procedures in the U.S. and approximately 4 million annual procedures worldwide. Motus GI believes the Pure-Vu® System may improve outcomes and lower costs for hospitals by reducing the time to successful colonoscopy, minimizing delayed and incomplete procedures, and improving the quality of an exam. In clinical studies to date, the Pure-Vu® System significantly increased the number of patients with an adequate cleansing level, according to the Boston Bowel Preparation Scale Score, a validated assessment instrument.

For more information, visit www.motusgi.com and connect with the Company on Twitter, LinkedIn and Facebook.

Forward-Looking Statements

This press release contains certain forward-looking statements. Forward-looking statements are based on the Company's current expectations and assumptions. The Private Securities Litigation Reform Act of 1995 provides a safe-harbor for forward-looking statements. These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms, including without limitation, risks inherent in the development and commercialization of potential products, uncertainty in the timing and results of clinical trials or regulatory approvals, maintenance of intellectual property rights or other risks discussed in the Company's Form 10-K filed on March 26, 2019, and its other filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Media Contact:
Erich A. Sandoval
Lazar Partners
(917) 497-2867
esandoval@lazarpartners.com

Investor Contact:
Jenene Thomas
Jenene Thomas Communications, LLC
(833) 475-8247
mots@jtcir.com