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 12, 2017

MILESTONE SCIENTIFIC INC.
(Exact name of Registrant as specified in its charter)

Delaware	001-14053	13-3545623
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

220 South Orange Avenue, Livingston Corporate Park, Livingston, New Jersey 07034
(Address of principal executive office) (Zip Code)

Registrant's telephone number, including area code (973) 535-2717

(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:

[ ] Written communications 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 communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications 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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. [ ]

Item 8.01. Other Events.

On June 12, 2017, Milestone Scientific Inc. issued a press release announcing that its CompuFlo® Epidural Computer Controlled Anesthesia System has received 510(k) clearance from the U.S. Food and Drug Administration. The press release is filed as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated June 12, 2017

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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.

Dated: June 12, 2017

MILESTONE SCIENTIFIC INC.

By: /s/ Joseph D'Agostino
Joseph D'Agostino
Chief Financial Officer

Exhibit 99.1

Contact:

David Waldman or Natalya Rudman
Crescendo Communications, LLC
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MILESTONE SCIENTIFIC ANNOUNCES 510(k) FDA CLEARANCE FOR COMPUFLO® EPIDURAL INSTRUMENT

LIVINGSTON, NJ, June 12, 2017 -- Milestone Scientific Inc. (NYSE: MLSS) today announced that the CompuFlo® Epidural Computer Controlled Anesthesia System has received 510(k) clearance from the U.S. Food and Drug Administration (FDA). The CompuFlo® Epidural System provides anesthesiologists and other Health Care Providers for the first time, the ability to quantitatively determine and document the pressure at the needle tip in real-time. The CompuFlo® Epidural's proprietary DPS Dynamic Pressure Sensing Technology™ (DPS) allows the CompuFlo® Epidural to provide objective visual and audible in-tissue pressure feedback that allows anesthesiologists to identify the epidural space.

"We are delighted to receive marketing clearance from the FDA, which is considered globally to be the regulatory gold standard in premarket review," commented Leonard Osser, Chief Executive Officer of Milestone Scientific. "I would like to thank all the employees, advisors, key-opinion leaders (KOL) and other stakeholders that were instrumental in helping us to achieve this major milestone."

"Looking ahead, we are now focused on reaching out to the top KOLs in the U.S., as we have been doing successfully across Europe. The CompuFlo® Epidural System's ease of use allows use by medical professionals with varying levels of experience, which further drives the value proposition of this technology. In addition, due to what we see as the device's add-on value proposition, we plan to seek reimbursement codes over and above those already in place for traditional epidural procedures."

This clearance was supported by the COMPASS Study (CompuFlo® Assessment Study), which was a prospective, randomized, controlled, parallel group, multicenter, pivotal study to assess the safety and effectiveness of epidural space verification with the CompuFlo® Epidural Instrument. The primary objective of the COMPASS study was to determine whether the success rate of performance of lumbar epidural anesthesia with the CompuFlo Epidural to identify the epidural space is equivalent to performance of lumbar epidural anesthesia with the LOR technique. The clinical study enrolled 400 patients, of which two-hundred-forty subjects (240) required epidural procedure as part of the chronic pain management and one-hundred-sixty (160) required epidural procedure for acute pain management during labor and delivery. The CompuFlo® Epidural with Dynamic Pressure Sensing Technology resulted in the anesthesiologists objectively identifying the epidural space with 99% success on the first attempt. The COMPASS study involved use of the CompuFlo Epidural in 21 obese subjects (BMI > 31), with performance in this group found to be comparable to the performance seen in patients with lower BMIs. However due to the relatively small sample size of obese patients studied, the safety and effectiveness profile in this subgroup of patients is not fully known.

Based on the nonclinical and clinical tests conducted, it was demonstrated the the CompuFlo Epidural device is as safe, as effective and performs as well as or better than the legally marketed predicate devices**.**

The overall results of the COMPASS study demonstrated that the CompuFlo® Epidural can serve as an everyday epidural needle placement confirmation solution.

About Milestone Scientific Inc.

Milestone Scientific Inc. (MLSS) is a leading medical research and development company that designs and patents innovative injection technologies. Milestone's computer-controlled systems are designed to make injections precise, efficient, and virtually painless. For more information please visit our website: www.milestonescientific.com.

The CompuFlo® Epidural Computer Controlled Anesthesia System is intended for use with an epidural needle for the real-time verification of needle tip placement in the lumbar epidural space in patients over age of 18 who are required to have epidural needle placement as part of a medically necessary, in-patient or out-patient procedure, as established by their Health Care Provider. Once Health Care Provider verifies the epidural needle placement in the lumbar epidural space, CompuFlo® Epidural Computer Controlled Anesthesia System is disconnected and the HCP continues with the medical procedure.

The CompuFlo Epidural is contraindicated in the following situations:

- The CompuFlo Epidural must not be used in situations when epidural access is medically contraindicated as established by Health Care Provider.
- The CompuFlo Epidural must not be used on a patient that has a skin condition (i.e., hemangioma, scleroderma, psoriasis, rash, open wound or tattoo) in their lumbar region greater than 4 cm^2.
- The CompuFlo Epidural must not be used on a patient who had prior back surgery in lumbar area that would prevent epidural access.
- The CompuFlo Epidural System is not intended to be used to Infuse Medication. The safety and effectiveness of infusing medication has not been evaluated.

Safe Harbor Statement

This press release contains forward-looking statements regarding the timing and financial impact of Milestone's ability to implement its business plan, expected revenues, timing of regulatory approvals and future success. These statements involve a number of risks and uncertainties and are based on assumptions involving judgments with respect to future economic, competitive and market conditions, future business decisions and regulatory developments, all of which are difficult or impossible to predict accurately and many of which are beyond Milestone's control. Some of the important factors that could cause actual results to differ materially from those indicated by the forward-looking statements are general economic conditions, failure to achieve expected revenue growth, changes in our operating expenses, adverse patent rulings, FDA or legal developments, competitive pressures, changes in customer and market requirements and standards, and the risk factors detailed from time to time in Milestone's periodic filings with the Securities and Exchange Commission, including without limitation, Milestone's Annual Report for the year ended December 31, 2016. The forward looking statements in this press release are based upon management's reasonable belief as of the date hereof. Milestone undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

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