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

September 4, 2018
Date of Report (Date of earliest event reported)

HELIUS MEDICAL TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**001-38445**	**36-4787690**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

(Exact name of registrant as specified in charter)

642 Newtown Yardley Road, Suite 100
Newtown, Pennsylvania, 18940
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (215) 944-6100

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 14a12 under the Exchange Act (17 CFR 240.14a12)
☐ Precommencement communications pursuant to Rule 14d2(b) under the Exchange Act (17 CFR 240.14d2(b))
☐ Precommencement communications pursuant to Rule 13e4(c) under the Exchange Act (17 CFR 240.13e4(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 7.01 Regulation FD Disclosure

On September 4, 2018, Helius Medical Technologies, Inc. (the "Company") issued a press release announcing the submission of a request to the U.S. Food and Drug Administration ("FDA") for de novo classification and 510(k) clearance for the Portable Neuromodulation Stimulator ("PoNS®") device with the FDA. A copy of the press release is furnished herewith as Exhibit 99.1.

The information set forth in this Item 7.01 and in the press release attached hereto as Exhibit 99.1, is deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information set forth in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, except to the extent that the Company specifically incorporates it by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press release dated September 4, 2018

SIGNATURE

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.

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: September 4, 2018

By: /s/ Joyce LaViscount
Joyce LaViscount, Chief Financial Officer

Helius Medical Technologies Submits Request for FDA 510(k) Clearance of the PoNS™ Device

NEWTOWN, PA., September 4, 2018 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (NASDAQ:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced that the Company has submitted a request to the U.S. Food and Drug Administration ("FDA") for de novo classification and 510(k) clearance of the Portable Neuromodulation Stimulator (PoNS™) device.

"Helius is excited to announce the submission of our request for de novo classification and 501(k) clearance of the PoNS device for the treatment of chronic balance deficit due to mild- to moderate-traumatic brain injury," said Philippe Deschamps, Helius' President, CEO and Chairman. "This important milestone is the result of many years of hard work from the Helius team, and it brings us one step closer to making our novel PoNS Treatment available for U.S. patients who suffer from the potentially disabling effects of TBI-related chronic balance disorder."

The Company's request for de novo classification and 510(k) clearance is supported by clinical data from two double-blind, randomized, controlled trials demonstrating the PoNS device's safety and efficacy, with combined enrollment of 163 patients. It is also informed by feedback provided by FDA during pre-submission meetings that focused on the Company's trial designs, clinical data and design verification testing.

Mr. Deschamps continued: "Looking ahead, the Company is focused on laying the groundwork for the commercial launch of our PoNS Treatment following FDA clearance and pursuing regulatory clearances in Canada, Australia, Europe."

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a neurotech company focused on neurological wellness. The Company's purpose is to develop, license and acquire unique and non-invasive platform technologies that amplify the brain's ability to heal itself. The Company's first product in development is the Portable Neuromodulation Stimulator (PoNS). For more information, visit www.heliusmedical.com.

About the PoNS Device and PoNS Treatment

The Portable Neuromodulation Stimulator (PoNS) is an investigational, non-invasive, medical device.

PoNS Treatment is the first and only tongue-delivered neuromodulation that combines stimulation of cranial nerves with physical and cognitive therapy to restore lost neurological function. The Company's trials investigating the PoNS in traumatic brain injury are more fully discussed in the

Company’s disclosure materials, including its Annual Report on Form 10-K and other filings with the United States Securities and Exchange Commission.

Cautionary Disclaimer Statement:

Certain statements in this news release are not based on historical facts and constitute forward-looking statements or forward-looking information within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Canadian securities laws. All statements other than statements of historical fact included in this news release are forward-looking statements that involve risks and uncertainties. Such forward-looking statements include, among others, statements regarding the potential clearance by the FDA of the Company’s regulatory submission and the future commercial launch of the PoNS device.

Forward-looking statements are often identified by terms such as “will”, “may”, “should”, “anticipate”, “expects”, “estimate”, “intend” and similar expressions.

There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements. Important factors that could cause actual results to differ materially from the Company’s expectations include the uncertainties associated with the FDA regulatory approval process, including the possibility that the FDA may not find the Company’s regulatory submission sufficient to support clearance, the Company’s need to raise additional capital to achieve its business objectives and other risks detailed from time to time in the filings made by the Company with securities regulators.

The reader is cautioned that assumptions used in the preparation of any forward-looking statements may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company. The reader is cautioned not to place undue reliance on any forward-looking statement. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. Risks and uncertainties about the Company’s business are more fully discussed in the Company’s disclosure materials, including its Annual Report on Form 10-K for the year ended December 31, 2017, its Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 and its other filings with the United States Securities and Exchange Commission and the Canadian securities regulators and which can be obtained from either at www.sec.gov or www.sedar.com.

The forward-looking statements contained in this news release are made as of the date of this news release and the Company assumes no obligation to update any forward-looking statement or to update the reasons why actual results could differ from such statements except to the extent required by law.

The Toronto Stock Exchange has not reviewed and does not accept responsibility for the adequacy or accuracy of the content of this news release.

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