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

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of December, 2020.

Commission File Number: **001-38524**

Titan Medical Inc.
(Exact Name of Registrant as Specified in Charter)

155 University Avenue, Suite 750
Toronto, Ontario M5H 3B7
Canada
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.
Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):____

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ____

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

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, thereunto duly authorized.

TITAN MEDICAL INC.
(Registrant)

Date: December 30, 2020

By: */s/ Monique Delorme*
Name: Monique Delorrme
Title: Chief Financial Officer

EXHIBIT INDEX

99.1	News Release dated December 30, 2020.

Titan Medical Provides Regulatory Update

TORONTO--(BUSINESS WIRE)--December 30, 2020--**Titan Medical Inc. (“Titan” or the “Company”) (TSX: TMD) (Nasdaq: TMDI)**, a medical device company focused on the design and development of surgical technologies for robotic single access surgery, announces that the Company has received a written response from the U.S. Food & Drug Administration (“FDA”) to its Request for Information in accordance with Section 513(g) of the U.S. Federal Food, Drug and Cosmetic Act (“FD&C Act”), regarding the regulatory requirements applicable to its robotically assisted surgical device (“RASD”), the Enos™ Robotic Single Access System. While the FDA's response to a 513(g) request does not constitute a classification decision, the FDA has indicated that, based on information provided to the agency, the Enos system is appropriate for classification through the De Novo pathway.

“The timely response from the FDA provides additional information regarding the agency’s position on potential predicate RASD systems along with the intended use and the technology embodied in the Enos system. These insights will help guide our regulatory strategy so that we can most efficiently allocate our resources to achieve U.S. market clearance,” said David McNally, President and Chief Executive Officer of Titan. “At this time, given the information available to us, we do not anticipate our likely pursuit of the De Novo pathway would materially affect our previously stated milestones or budgets for 2021. During the first quarter of 2021, we plan on further communications with the FDA, including filing a Pre-Submission, with the intent of clarifying any requirements for our planned Investigational Device Exemption studies and any potential impact on previously established timelines and forecasted costs.”

Requests for Information made pursuant to Section 513(g) of the FD&C Act require the FDA to provide information about the classification and the regulatory requirements that may be applicable to a particular device. FDA responses to such requests represent the FDA's best judgment about how a device would be regulated, based upon review of information provided by a requester, including the description of the device and its intended use. The FDA's response to a 513(g) request is not a classification decision for a device and does not constitute FDA clearance or approval for commercial distribution. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act, such as a classification obtained in response to a premarket notification submitted in accordance with Section 510(k) of the FD&C Act, commonly known as a 510(k) submission, or a classification obtained for novel devices under section 513(f)(2) of the FD&C Act, also known as a De Novo submission.

In view of the FDA's written response and other information available to the Company at this time, the Company would likely proceed with a De Novo classification request for its Enos system in place of a 510(k) submission. Should the FDA grant the De Novo classification request, the Class II device would be cleared to be marketed. In addition, a new classification regulation will be established, and the new device may then serve as a predicate device for 510(k) submissions of future devices of the same type. Should the De Novo classification request be declined, the device, as a Class III device, would require pursuit of a premarket approval under Section 515 of the FD&C Act, also known as a PMA, requiring additional time and expense.

About Titan Medical

Titan Medical Inc., a medical device company headquartered in Toronto, is focused on developing robotic assisted technologies for application in single access surgery. The Enos system, by Titan Medical, is being developed with dual 3D and 2D high-definition vision systems, multi-articulating instruments, and an ergonomic surgeon workstation. With the Enos system, Titan intends to initially pursue gynecologic surgical indications.

Certain of Titan's robotic assisted surgical technologies and related intellectual property have been licensed to Medtronic plc, while retaining world-wide rights to commercialize the technologies for use with the Enos system.

Enos™ is a trademark of Titan Medical Inc.

For more information, visit www.titanmedicalinc.com.

Forward-Looking Statements of Titan Medical

This news release contains “forward-looking statements” within the meaning of applicable Canadian and U.S. securities laws. Such statements reflect the current expectations of management of the Company’s future growth, results of operations, performance and business prospects and opportunities. Wherever possible, words such as “may”, “would”, “could”, “will”, “anticipate”, “believe”, “plan”, “expect”, “intend”, “estimate”, “potential for” and similar expressions have been used to identify these forward-looking statements, including references to: the Company’s focus on the design and development of surgical technologies for robotic single access surgery; the Company being focused on developing robotic assisted technologies for application in single access surgery; the Enos system being developed to become the new standard of care in robotic single access surgery with dual 3D and 2D high-definition vision systems, multi-articulating instruments, and an ergonomic surgeon workstation; the FDA’s response to the Company’s 513(g) request indicating that the Enos system is appropriate for classification through the De Novo pathway; the FDA guidance will help guide the Company’s regulatory strategy so that it can allocate resources to achieve U.S. market clearance; pursuit of the De Novo pathway will not materially affect the Company’s previously stated milestones or budgets for 2021; during the first quarter of 2021 the Company plans on further communications with the FDA, including filing a Pre-Submission; the Company will likely proceed with a De Novo classification request for its Enos system in place of a 510(k) submission; were the FDA to grant the De Novo classification request, the Class II device would be cleared to be marketed; the Enos system may serve as a predicate device for 510(k) submissions of future devices of the same type; were the De Novo classification request declined, as a Class III device, the device would require pursuit of a premarket approval under Section 515 of the FD&C Act, requiring additional time and expense; and the Company’s intention to initially pursue gynecologic surgical indications. These statements reflect management’s current beliefs with respect to future events and are based on information currently available to management. Forward-looking statements involve significant risks, uncertainties and assumptions. Many factors could cause the Company’s actual results, performance or achievements to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements, including, without limitation, those listed in the “Risk Factors” section of the Company’s Annual Report on Form 20-F dated April 2, 2020 (which may be viewed at www.sedar.com and at www.sec.gov). Should one or more of these risks or uncertainties materialize, or should assumptions underlying the forward-looking statements prove incorrect, actual results, performance, or achievements may vary materially from those expressed or implied by the forward-looking statements contained in this news release. These factors should be considered carefully, and prospective investors should not place undue reliance on the forward-looking statements. Although the forward-looking statements contained in the news release are based upon what management currently believes to be reasonable assumptions, the Company cannot assure prospective investors that actual results, performance or achievements will be consistent with these forward-looking statements. Except as required by law, the Company expressly disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

Contacts

Monique L. Delorme
Chief Financial Officer
+1-416-548-7522
investors@titanmedicalinc.com