UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): May 9, 2007

LeMaitre Vascular, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware **(State or Other Jurisdiction of Incorporation)**		
001-33092 **(Commission File Number)**		**04-2825458** **(IRS Employer Identification No.)**
63 Second Avenue **Burlington, Massachusetts** **(Address of Principal Executive Offices)**		**01803** **(Zip Code)**

(781) 221-2266
(Registrant's Telephone Number, Including Area Code)

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))

Item 7.01 Regulation FD Disclosure

On May 9, 2007, the Company issued a press release announcing approval from the United States Food and Drug Administration for an investigational device exemption supplement to conduct its pivotal clinical trial to evaluate the safety and effectiveness of the UniFit Abdominal Stent Graft in the treatment of aorto, aorto-iliac and/or iliac aneurysms, which the Company refers to as the UNITE trial. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information set forth in this Item 7.01, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events

On May 9, 2007, the Company announced that it received approval from the United States Food and Drug Administration (FDA) for an investigational device exemption (IDE) supplement to conduct its pivotal clinical trial to evaluate the safety and effectiveness of the UniFit Abdominal Stent Graft in the treatment of aorto, aorto-iliac and/or iliac aneurysms, which the Company refers to as the UNITE trial. The Company had previously received conditional FDA approval for its IDE supplement. As permitted by this conditional approval, the Company had previously commenced enrollment at a small number of institutions.

The Company intends to enroll 90 patients in up to 14 centers. These patients must be followed for at least one year prior to LeMaitre Vascular's submission to the FDA of an application for premarket application (PMA) approval. The primary effectiveness endpoint of the study is based on aneurysm exclusion as evaluated through one-year follow-up. The UNITE study compares the safety and efficacy of the UniFit Abdominal Stent Graft against open surgical abdominal aorta repair.

The FDA's IDE approval applies only to the investigational use of UniFit Abdominal Stent Grafts that have been sterilized with ethylene oxide gas. LeMaitre Vascular also sterilizes its UniFit Abdominal Stent Grafts sold outside the United States with hydrogen peroxide, a newer and generally faster means of sterilizing medical devices. The Company intends to continue to work with the FDA to resolve their questions regarding this method of sterilization with the intent of ultimately seeking PMA approval of the hydrogen peroxide-sterilized UniFit Abdominal Stent Graft.

Forward-Looking Statements

This Current Report on Form 8-K contains forward looking statements that are mare pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to the enrollment in the UNITE study, the likelihood that the UNITE study will successfully meet its endpoints and the possibility of receiving approval for the sale of the UniFit Abdominal Stent Graft in the United States. Although the Company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, these forward-looking statements are neither promises nor guarantees. There can be no assurance that the results of the UNITE trial will support a PMA or that the FDA will approve the UniFit Abdominal Stent Graft for sale the United States. The Company's business is subject to significant risks and uncertainties and there can be no assurance that its actual results will not differ materially from its expectations. These risks and uncertainties include, among others: the risk that the results of the Company's UNITE study will be unfavorable; the risk that these results, even if favorable, will not be accepted by the FDA or other relevant agencies and the device will not be approved for sale in the relevant timeframe, if at all; risks associated with the Company's ability to successfully commercialize its UniFit Abdominal Stent Graft in the United States if the device is approved for use in the United States; and other risk factors that are discussed in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission. The forward-looking statements made in this Current Report on Form 8-K are made only as of the date hereof and the Company disclaims any intention or responsibility for updating predictions or expectations contained in this release.

Item 9.01 Financial Statements and Exhibits.

The following exhibit is furnished as part of this report, where indicated:

(d) Exhibits.

Exhibit No	Description
99.1	Press release issued by LeMaitre Vascular, Inc. on May 9, 2007, furnished herewith.

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.

LEMAITRE VASCULAR, INC.

Dated: May 11, 2007

By: /s/ Aaron M. Grossman
Name: Aaron M. Grossman
Title: Vice President & General Counsel

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press release issued by LeMaitre Vascular, Inc. on May 9, 2007, furnished herewith.

LeMaitre Vascular Receives IDE Approval to Begin the 'Unite' UniFit Abdominal Stent Graft Pivotal Study

BURLINGTON, Mass., May 9 /PRNewswire-FirstCall/ — LeMaitre Vascular, Inc. (Nasdaq: LMAT) today announced that it has received approval from the United States Food and Drug Administration (FDA) for an investigational device exemption (IDE) supplement to conduct its UNITE Aorto-Uni-Iliac Stent Graft Clinical Trial. This pivotal study will evaluate the safety and effectiveness of the company's UniFit Abdominal Stent Graft in the treatment of aorto, aorto-iliac, and/or iliac aneurysms. LeMaitre Vascular had previously received conditional FDA approval for its IDE supplement.

"Although we had initiated two study sites based upon conditional approval, many other hospitals, though eager to participate, have been waiting for the FDA to remove conditions. We expect that this new approval will help us drive enrollment through a broad range of study sites," said George W. LeMaitre, the company's Chairman, President and CEO. "We believe surgeons need a singled-body aorto-uni-iliac stent graft to help combat aneurysmal disease and we are excited to begin implanting devices in our pivotal study."

LeMaitre Vascular intends to enroll 90 patients in up to 14 centers. These patients must be followed for at least one year prior to LeMaitre Vascular's submission to the FDA of an application for PMA approval. The primary effectiveness endpoint of the study is based on aneurysm exclusion as evaluated through one-year follow-up. The UNITE study compares the safety and efficacy of the UniFit Abdominal Stent Graft against open surgical abdominal aorta repair, because there are currently no aorto-uni-iliac endovascular stent grafts indicated for the primary treatment of aorto, aorto-iliac, and/or iliac aneurysms.

The UniFit Abdominal Stent Graft is a single-bodied aorto-uni-iliac stent graft used to treat an aortic aneurysm, a weakening and ballooning of the aorta, through a minimally invasive endovascular procedure. The device's encapsulated design prevents its stents from contacting the blood stream or the vessel wall. This design allows a wider range of stent graft sizes, including tapered and custom grafts, to fit a wider range of patient anatomies than many competing products. The UniFit Abdominal Stent Graft is currently sold in the European Union and a small number of other foreign jurisdictions and is not available for sale in the United States.

The FDA's IDE approval applies only to the investigational use of UniFit Abdominal Stent Grafts that have been sterilized with ethylene oxide gas, a relatively common means of sterilizing medical devices. LeMaitre Vascular also sterilizes its UniFit Abdominal Stent Grafts sold outside the United States with hydrogen peroxide, a newer and generally faster means of sterilizing medical devices. Hydrogen peroxide sterilization enables the more rapid production of customized stent grafts. LeMaitre Vascular intends to continue to work with the FDA to resolve their questions regarding this method of sterilization with the intent of ultimately seeking PMA approval of the hydrogen peroxide-sterilized UniFit Abdominal Stent Graft.

About LeMaitre Vascular

LeMaitre Vascular develops, manufactures and markets medical devices for the treatment of peripheral vascular disease. The company's principal executive offices are located at 63 Second Avenue, Burlington, Massachusetts 01803.

Certain statements set forth above that are not clearly historical in nature are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to the likelihood and timing of enrollment in the UNITE study, the likelihood that the UNITE study will successfully meet its endpoints, the possibility of receiving approval for the sale of the UniFit Abdominal Stent Graft in the United States, and the potential market demand in the United States for the UniFit Abdominal Stent Graft. Although LeMaitre Vascular believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, these forward-looking statements are neither promises nor guarantees. LeMaitre Vascular's business is subject to significant risks and uncertainties and there can be no assurance that its actual results will not differ materially from its expectations. These risks and uncertainties include, among others: the risk that the results of LeMaitre Vascular's UNITE study will be unfavorable; the risk that these results, even if favorable, will not be accepted by the FDA or other relevant agencies and the device will not be approved for sale in the relevant timeframe, if at all; risks associated with LeMaitre Vascular's ability to successfully commercialize its UniFit Abdominal Stent Graft in the United States if the device is approved for use in the United States; and other risk factors that are discussed in LeMaitre Vascular's Annual Report on Form 10-K filed with the Securities and Exchange Commission. The forward-looking statements made in this release are made only as of the date hereof and LeMaitre Vascular disclaims any intention or responsibility for updating predictions or expectations contained in this release.

SOURCE :
LeMaitre Vascular, Inc.

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