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): November 17, 2009

SafeStitch Medical, Inc.

(Exact name of registrant as specified in its charter)

Delaware	0-19437	11-2962080
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
4400 Biscayne Blvd., Suite A-100, Miami, Florida		33137
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: 305-575-4145

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:

[ ] 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))

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Item 7.01 Regulation FD Disclosure.

On November 17, 2009, SafeStitch Medical, Inc. (the "Company") issued a press release announcing that the United States Food & Drug Administration has approved the Company’s domestic marketing of its AMID StaplerTM for use in general surgery procedures for fixation of mesh, in the repair of hernia defects and in other surgical specialties for the approximation of tissues, including skin. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" with the Securities and Exchange Commission 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act. This Current Report on Fo rm 8-K shall not be deemed an admission as to the materiality of any information contained herein, including Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number Description

99.1 Press release dated November 17, 2009.

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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.

SafeStitch Medical, Inc.

November 17, 2009

By: Adam S. Jackson

Name: Adam S. Jackson
Title: Chief Financial Officer

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Exhibit Index

Exhibit No.	Description
99.1	Press release dated November 17, 2009

SafeStitch Medical, Inc. Receives FDA Clearance to Market the AMID Stapler™ for Hernia Repairs

MIAMI—(BUSINESS WIRE)—SafeStitch Medical, Inc. (OTCBB: SFES — News) announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") to market its AMID Stapler™ in the U.S. with the intended use in general surgery procedures for fixation of mesh, in the repair of hernia defects and in other surgical specialties for the approximation of tissues, including skin. The AMID Stapler™ is the first surgical stapler designed specifically for use in inguinal hernia repairs using the Lichtenstein method, in which mesh is implanted to reinforce the groin floor. The Company has also applied for clearance to market the AMID Stapler™ in the European Economic Community and other areas outside of the U.S.

SafeStitch designed the stapler in collaboration with Dr. Parviz Amid, an early pioneer and world-renowned teacher of the Lichtenstein repair. Dr. Charles J. Filipi, SafeStitch's Medical Director and former President of the American Hernia Society, noted that "approximately one million hernia repairs are performed in the U.S. each year, and the Lichtenstein repair is used in 60% to 70% of inguinal hernia repairs worldwide. Based on our preliminary clinical experience, we believe the AMID Stapler™ will make the Lichtenstein repair faster and will be especially attractive to surgeons presently affixing mesh and closing incisions with sutures."

"The AMID Stapler™ has an angled staple delivery for safety and better visibility, patented mesh manipulators for easy and safe mesh placement, and has 17 box–shaped, sharp-tipped titanium staples designed specifically for this repair" explained Dr. Stewart Davis, SafeStitch's COO. Dr. Davis added that "although the AMID Stapler™ was designed for inguinal hernia repairs, it is versatile and can also be used to perform ventral hernia repairs and to close skin for either type of repair."

Jeffrey Spragens, SafeStitch's President and CEO, noted that, "this FDA clearance marks the completion of the development phase for SafeStitch's first four products: the SMART Dilator™, Standard BiteBlock, Airway BiteBlock and the AMID Stapler™. We will now begin our commercialization efforts for these products, starting with the launch of the AMID Stapler™. Our product development efforts are now fully focused on SafeStitch's minimally invasive gastroplasty devices for obesity and GERD procedures. We have successfully completed our pre-clinical laboratory studies with these devices, and we are preparing IDE applications for FDA clearance to conduct multicenter clinical trials."

About SafeStitch Medical, Inc.

Miami-based SafeStitch Medical, Inc. is a medical device company primarily developing endoscopic and minimally invasive surgical devices. SafeStitch's product portfolio includes endoscopic gastroplasty devices for bariatric (obesity) surgery and repair of gastroesophageal reflux disorder (GERD), as well as the AMID Stapler™, Standard BiteBlock, Airway BiteBlock and SMART Dilator™. The Company has also started development of devices for excision and diagnosis of Barrett's esophagus and natural orifice transluminal endoscopic surgery (NOTES). Information about the Company may be found on its website at: www.safestitch.com.

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding our product development and commercialization efforts, and our ability to significantly improve clinical outcomes in patients, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors, including those described in our filings with the Securities and Exchange Commission, could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include that the design of the AMID Stapler ™ may not have the versatility or perform as anticipated or make the hernia repair procedure easier, faster or safer, or reduce post-operative pain, that we may not receive clearance to market the AMID Stapler ™ in the European Economic Community or other areas outside of the U.S., that the commercialization of the AMID Stapler™ or any of other devices may be delayed or may be unsuccessful, that we will be unable to successfully develop and commercialize our minimally invasive gastroplasty devices for obesity and GERD procedures, that our devices under development may not achieve the expected results or effectiveness and may not generate data that would support their approval or marketing, that others may develop products and devices, including other devices for hernia repair, obesity or GERD procedures, which are superior to our devices, and that our devices may not have advantages over presently marketed products or devices or products or devices under development by others. In addition, forward-looking statements may also be adversely affected by risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements, except as required under applicable law. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

Contact: SafeStitch Medical, Inc., Miami

Dr. Stewart B. Davis, 305-575-4145