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

February 17, 2009
Date of Report (Date of earliest event reported)

SAFESTITCH MEDICAL, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	**0-19437**	**11-2962080**
(State of Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

4400 Biscayne Boulevard, Suite 670, Miami, Florida	**33137**
(Address of principal executive offices)	(Zip Code)

(305) 575-4145
(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 (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure

On February 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 SMART Dilator™ for dilation of strictures of the esophagus under endoscopic visualization in adults 18 years or older. 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 Form 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 February 17, 2009.

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 thereunto duly authorized.

SAFESTITCH MEDICAL, INC.

By: /s/ Adam S. Jackson
Name: Adam S. Jackson
Title: Chief Financial Officer

Date: February 18, 2009

Exhibit Index

Exhibit Number	Description
99.1	Press release dated February 17, 2009.

SafeStitch Medical, Inc. Announces FDA Approval to Market Its SMART Dilator™

MIAMI--(BUSINESS WIRE)--SafeStitch Medical, Inc. (OTCBB: SFES - News) announced that the U.S. Food and Drug Administration ("FDA") has approved the Company's 510(k) application to begin U.S. marketing of its SMART Dilator™, the first esophageal dilator to indicate the pressure level being applied at the esophageal stricture. "Having this information should reduce the incidence of esophageal perforation – a devastating complication for patients – in the approximately 2,000,000 esophageal dilations performed annually worldwide" said Dr. Charles J. Filipi, SafeStitch's Medical Director. Dr. Filipi added that "the SMART Dilator is expected to simplify and shorten the dilation process, which will help endoscopic clinics operate more safely and efficiently."

Jeffrey Spragens, SafeStitch's President and CEO, noted that "this FDA approval marks the completion of the development phase of our three introductory products: the SMART Dilator™, Standard BiteBlock and Airway BiteBlock - and we will now begin our commercialization efforts for these products. Our product development efforts are now focused on SafeStitch's hernia skin stapler and its minimally invasive gastroplasty devices for obesity and GERD procedures."

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 a hernia skin stapler, a standard bite block, an airway bite block and the 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 efforts, our ability to significantly improve clinical outcomes in patients, and our ability to develop a preclinical pipeline of novel agents for ophthalmic diseases, 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 could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, forward-looking statements may also be adversely affected by 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:
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