

UROPLASTY INC
Form 8-K
September 14, 2006

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**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: September 14, 2006

UROPLASTY, INC.

(Exact name of registrant as specified in charter)

000-20989

(Commission File No.)

41-1719250

(IRS Employer Identification No.)

Minnesota

(State or other jurisdiction of incorporation or organization)

5420 Feltl Road

Minnetonka, Minnesota 55343

(Address of principal executive offices)

952-426-6140

(Registrant's telephone number, including area code)

Not Applicable

(Former Name and Address)

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 of 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 8.01 Other Events

On September 13, 2006 we issued a press release announcing that we received an approvable letter from the U.S. Food and Drug Administration (FDA) relating to our pre-market approval (PMA) application for Macroplastique Implants for the treatment of female stress urinary incontinence.

The receipt of the approvable letter follows FDA's completion of the scientific review of the safety and efficacy of Macroplastique. The FDA determined that the PMA is approvable subject to our manufacturing facilities, methods and controls being audited by the FDA and in compliance with applicable Quality System Requirements. The FDA is currently auditing our manufacturing facilities in Minneapolis, Minnesota and Eindhoven, The Netherlands.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 13, 2006 (filed 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, thereunto duly authorized.

Dated: September 14, 2006

UROPLASTY, INC.

By: /s/ Mahedi A. Jiwani
Mahedi A. Jiwani
Vice President, Chief Financial Officer
and Treasurer