

MENTOR CORP /MN/
Form 8-K
November 03, 2005

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):

October 24, 2005

MENTOR CORPORATION

(Exact name of registrant as specified in its charter)

Minnesota

(State or other jurisdiction of
incorporation)

0-7955

(Commission File No.)

41-0950791

(IRS Employer I.D. No.)

201 Mentor Drive
Santa Barbara, California 93111
(Address of principal executive offices)

Registrant's telephone number, including area code:
(805) 879-6000

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):

- ☐ 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 8.01 Other Events

During the course of October 24 through October 25, 2005, Mentor Corporation ("the Company") mistakenly sent a fax message with an attached letter, which was in draft form, to a portion of the investigators participating in the Company's adjunct study for its silicone gel-filled breast implants. The draft letter attachment was intended to be sent only in the potential event of a notification from the Food and Drug Administration ("FDA") of an approval of the Company's pre-market approval ("PMA") application for its silicone gel-filled breast implants, and was clearly marked "[SAMPLE LETTER - Contingent on Final FDA Approval of Devices]". The fax message was prepared to inform adjunct study investigators of their subsequent obligations, and to address appropriate actions that would be required, in the event FDA approved the PMA application. Upon learning that the fax message with attachment was being sent in error, the Company immediately ceased sending it to the remaining study investigators. Subsequently, following discussions with the FDA, the Company took immediate steps to correct the error and sent follow-up correspondence to those study investigators on October 27, 2005. The Company understands that this issue was resolved to FDA's satisfaction.

The PMA for the Company's silicone gel-filled breast implants continues to be under review and has not been approved by the FDA. The Company intends to continue to work with the FDA during the course of its PMA review, but cannot speculate as to the outcome or timing of a decision.

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.

Date: November 2, 2005

MENTOR CORPORATION
/s/LOREN L. MCFARLAND
Loren L. McFarland
Chief Financial Officer