

ORASURE TECHNOLOGIES INC

Form 8-K

June 28, 2004

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): June 25, 2004

ORASURE TECHNOLOGIES, INC.

(Exact name of issuer as specified in charter)

DELAWARE
(State or Other Jurisdiction of
Incorporation or Organization)

001-16537
(Commission file number)

36-4370966
(I.R.S. Employer
Identification Number)

220 East First Street

Bethlehem, Pennsylvania 18015-1360

(Address of principal executive offices)

(610) 882-1820

(Registrant's telephone number, including area code)

Item 5 Other Events and Regulation FD Disclosure.

OraSure Technologies, Inc. (the Company) issued a press release on June 25, 2004, announcing that the U.S. Food and Drug Administration, through its Center for Devices and Radiological Health, has approved a waiver under the Clinical Laboratory Improvements Amendments of 1988 for the Company's OraQuick® Rapid HIV-1/2 Antibody Test. The information contained in the press release, dated June 25, 2004, is incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 7. Financial Statements, Pro Forma Financial Information and Exhibits.

(c) Exhibits

Exhibit Number	Description
99.1	Press Release dated June 25, 2004, announcing that the U.S. Food and Drug Administration, through its Center for Devices and Radiological Health, has approved a waiver under the Clinical Laboratory Improvements Amendments of 1988 for the Company's OraQuick® Rapid HIV-1/2 Antibody Test.

Signatures

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ORASURE TECHNOLOGIES, INC.

Date: June 28, 2004

By: /s/ Jack E. Jerrett

Jack E. Jerrett
Senior Vice President, General Counsel and Secretary

Index to Exhibits

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