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	**001-16537**	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission file number)**	**(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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Exhibit 99.1

OraSure Technologies, Inc.

diagnostic solutions for the new millennium

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ORASURE RECEIVES CLIA WAIVER
FOR ORAQUICK® RAPID HIV-1/2 ANTIBODY TEST

BETHLEHEM, PA – June 25, 2004 – OraSure Technologies, Inc. (NASDAQ NM:OSUR), the market leader in oral fluid diagnostics, announced today that the U.S. Food and Drug Administration ("FDA"), through its Center for Devices and Radiological Health, has approved a waiver under the Clinical Laboratory Improvements Amendments of 1988 ("CLIA") for the Company's OraQuick® Rapid HIV-1/2 Antibody Test.

Specifically, the test has been waived for use in detecting HIV-1 and HIV-2 antibodies in oral fluid, finger stick whole blood and venous whole blood samples. With this waiver, the OraQuick® HIV-1/2 test, which provides results in just 20 minutes, can be used by more than 180,000 sites in the United States, including outreach clinics, community-based organizations and physicians' offices.

"We are very excited about receiving the CLIA waiver so quickly and the opportunity to make the OraQuick® HIV-1/2 test available to all who need it," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "We believe this waiver represents the final step needed to make our new OraQuick® HIV-1/2 test the most versatile and comprehensive rapid HIV test available to the widest possible range of customers in the United States. The OraQuick® HIV-1/2 test is expected to be available for sale in mid-August. We would again like to thank HHS Secretary Tommy Thompson for his leadership and the FDA for its dedication and hard work in helping make rapid HIV testing widely available in the fight against HIV/AIDS."

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About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays and other *in vitro* diagnostic tests, and other medical devices. These products are sold in the United States as well as internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities.

OraSure Technologies is the leading supplier of oral-fluid collection devices and assays to the life insurance industry and public health markets for the detection of antibodies to HIV-1. In addition, the Company supplies oral-fluid testing solutions for drugs of abuse testing. For more information on the Company, please go to www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to products, regulatory submissions and approvals, sales and markets. Actual results could be significantly different. Factors that could affect results include the ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to maintain new or existing product distribution channels (including OraSure's ability to implement a direct sales effort or other alternative distribution for OraQuick®); reliance on sole supply sources for critical product components; availability of related products produced by third parties; ability to obtain and timing of obtaining necessary regulatory approvals; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; ability to obtain licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; ability to complete consolidation or restructuring activities; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission ("SEC") filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2003, its Quarterly Reports on Form 10-Q, and its other filings with the SEC. Although forward-looking statements help to provide complete information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

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