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): September 9, 2003

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 announcing the receipt of U.S. Food and Drug Administration approval of the Company's OraQuick® Rapid HIV-1 Antibody Test for use with venipuncture whole blood samples. The information contained in the press release dated September 9, 2003 is incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibit 99.

Item 7. Financial Statements and Exhibits

(c) Exhibits

Exhibit Number	Description
99	Press Release dated September 9, 2003, announcing receipt by OraSure Technologies, Inc. of U.S. Food and Drug Administration approval of its OraQuick® Rapid HIV-1 Antibody Test for use with venipuncture whole blood samples.

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: September 9, 2003

By: /s/ JACK E. JERRETT

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

Index to Exhibits

Exhibit Number	Description
99	Press Release dated September 9, 2003, announcing receipt by OraSure Technologies, Inc. of receipt of U.S. Food and Drug Administration approval of its OraQuick® Rapid HIV-1 Antibody Test for use with venipuncture whole blood samples.

Exhibit 99

[LOGO] OraSure Technologies, Inc.
diagnostic solutions for the new millenium

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FDA APPROVES VENIPUNCTURE WHOLE BLOOD CLAIM FOR ORAQUICK®
RAPID HIV-1 ANTIBODY TEST

BETHLEHEM, PA – September 9, 2003 – OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, announced today that its OraQuick® Rapid HIV-1 Antibody Test has been approved by the U.S. Food and Drug Administration ("FDA") for use in detecting HIV-1 antibodies in venipuncture whole blood specimens.

This is the second claim approved by the FDA for the OraQuick® test. In November 2002, the Company received approval for use of the OraQuick® test with fingerstick whole blood specimens. The new approval for venipuncture whole blood is expected to expand the use of the test, especially in hospitals where venipuncture whole blood samples are routinely drawn from patients for testing. Sales of the OraQuick® test for use with venipuncture whole blood are subject to the completion of final product labeling incorporating this new claim, which is currently under review by the FDA.

"Receiving FDA approval of a venipuncture whole blood claim is another significant step in our quest to make OraQuick® the most versatile rapid HIV-1 test available in the U.S. market," said Mike Gausling, Chief Executive Officer of OraSure Technologies. "This approval should help open the door for hospitals to incorporate the OraQuick® test more readily when drawing venous whole blood specimens."

—more—

OraQuick® is the first rapid, point-of-care test approved by the FDA to detect antibodies to HIV-1 in fingerstick and venipuncture whole blood specimens within approximately 20 minutes. OraSure received FDA approval of the OraQuick® test for fingerstick whole blood on November 7, 2002. On January 31, 2003, OraSure received a CLIA waiver for the test, permitting its use by more than 180,000 sites in the United States, including outreach clinics, community-based organizations and physicians' offices.

OraSure is completing the clinical trials for usage of the OraQuick® device with oral fluid and plasma samples, and expects to file submissions for these claims with the FDA in the near future. In addition, OraSure has completed the necessary clinical trials and filed for FDA approval for use of the OraQuick® device to detect antibodies to a second type of the HIV virus, known as HIV-2. This action was taken by OraSure in anticipation of obtaining access to an HIV-2 patent license, either through another party or directly with the holder of certain patents covering the HIV-2 virus.

About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies and diagnostic products, including immunoassays and other *in vitro* diagnostic tests and other medical devices. These products are sold in the United States and certain foreign countries to various distributors, government agencies, clinical laboratories, physicians' offices, hospitals, 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 sales, markets, regulatory filings and approvals, and products. 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; 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; availability of 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, 2002, 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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