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 22, 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 filing of an application with the U.S. Food and Drug Administration for 510(k) clearance of its UP*link*® rapid point-of-care oral fluid drug detection system. The information contained in the press release dated September 22, 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 22, 2003, announcing the filing of an application with the U.S. Food and Drug Administration for 510(k) clearance of its UP*link*® rapid point-of-care oral fluid drug detection system.

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 23, 2003

By: /s/ JACK E. JERRETT

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

Index to Exhibits

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99	Press Release dated September 22, 2003, announcing the filing of an application with the U.S. Food and Drug Administration for 510(k) clearance of its UP*link*® rapid point-of-care oral fluid drug detection system.

Exhibit 99

[LOGO of OraSure Technologies, Inc.]

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OraSure Technologies Seeks FDA Clearance for
UP*link*® Oral Fluid NIDA-5 Drug Test System

BETHLEHEM, PA. – September 22, 2003—(BW HealthWire)—OraSure Technologies, Inc. (NASDAQ NM:OSUR), a market leader in oral fluid diagnostics, today announced that it has filed an application for 510(k) clearance with the U.S. Food and Drug Administration ("FDA") for its UP*link*® analyzer and oral fluid assays for the rapid, point-of-care detection of drugs of abuse commonly identified by the National Institute for Drug Abuse ("NIDA") as the NIDA-5, i.e., – cocaine, opiates, amphetamine/methamphetamine, PCP and marijuana.

UP*link*® is OraSure's first product platform based on its proprietary Up-Converting Phosphor Technology (UPT™). UP*link*® is a point-of-care system comprised of an oral fluid sample collector, test cassette, and analyzer, which can deliver instrument-read results for simultaneously detecting the full NIDA-5 panel of drugs in a single oral fluid sample. The Company believes the UP*link*® point-of-care oral fluid detection system will offer several important advantages over traditional lab-based urine drug tests, including reduced costs and turn around time, the ability to perform accurate drug testing for a full NIDA-5 panel virtually anywhere, treatment of test subjects with greater dignity, and reduced risk of sample adulteration.

OraSure intends to obtain FDA 510(k) clearance before it begins to market the UP*link*® detection system in the United States. The Company's submission is based on data demonstrating that the UP*link*® point-of-care oral fluid detection system provides safety and efficacy equivalent to that provided by another legally-marketed product – in this case, the Company's FDA-cleared, laboratory-based Intercept® oral fluid drug test.

"The filing of a 510(k) submission for the UP*link*® NIDA-5 drug detection system represents a significant milestone and is the result of an enormous effort by our research and development, manufacturing, quality and regulatory groups," said Dr. Sam Niedbala, OraSure's Executive Vice President and Chief Science Officer. "The UP*link*® system has performed well in our clinical trials, and we are excited about moving forward toward the commercialization of this important product."

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The Company has also obtained certification by Underwriters Laboratories Inc. (i.e. UL approval) that the UP*link*® analyzer meets certain industry safety and performance standards required for the international sale of electrical and light-emitting equipment, which will allow the Company to market the UP*link*® system around the world. OraSure expects to begin initial distribution of the UP*link*® drug detection system internationally through its development partner, Dräger Safety AG & Co. KGaA, primarily in the roadside testing and law enforcement markets in Europe and other countries. Dräger Safety is a leading supplier of breath alcohol detection equipment throughout the world.

OraSure Technologies currently manufactures and markets Intercept®, the only FDA-cleared, laboratory-based oral fluid drug test, which can detect the full NIDA-5 panel of drugs. Assuming FDA clearance of UP*link*® is received, the Company believes that its Intercept® laboratory test, when offered in combination with the UP*link*® rapid point-of-care detection system, will provide the Company's customers with a total oral fluid drug testing solution by allowing them the flexibility to test a single oral fluid sample for the full NIDA-5 panel of drugs either in a laboratory or at the point of care.

About Up-Converting Phosphor Technology (UPT™)

UPT™ is a proprietary label detection technology that is under development by OraSure Technologies and research partners, SRI International, Menlo Park, California, and Leiden University, The Netherlands. UPT™ uses phosphor particles that convert light from low energy (infrared) to high-energy visible light. This rare optical process, not found in nature, is expected to make UPT™ useful as a reporter label to detect a wide variety of targets including drugs of abuse, infectious diseases, cancer markers, food pathogens, cardiac risk markers, and DNA probes. UPT™ particles produce zero background interference, which has the potential to dramatically increase the potential sensitivity of any test system. In addition, the many colors of particles are expected to allow simultaneous detection of multiple biological markers. Development of UPT™ is not yet complete, and OraSure has not yet fully explored the potential applications of this technology platform. Additional research and development will be required in order to determine the full potential of UPT™.

About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices and tests and other diagnostic products using its proprietary technologies, 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 clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, government agencies, distributors, physicians' offices, and commercial and industrial entities. For more information on the Company, please visit www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including statements with respect to sales, markets, regulatory filings and approvals, technology and products. Actual results could be significantly different. Factors that could affect our 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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