

ORASURE TECHNOLOGIES INC

Form 8-K

December 18, 2003

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): December 18, 2003

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 December 15, 2003, announcing that it has submitted the additional data requested by the U.S. Food and Drug Administration (FDA) in support of an HIV-2 claim for its OraQuick[®] Rapid HIV-1 Antibody Test. The information contained in the press release is incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibit 99.1.

The Company also issued a press release on December 17, 2003, announcing that the FDA has successfully completed a facility inspection required for the transfer of the Company's in-house and third party contract manufacturing operations from Oregon to Bethlehem, Pennsylvania. The information contained in the press release is incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibit 99.2.

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

(c) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated December 15, 2003, announcing that the Company has submitted the additional data requested by the FDA in support of an HIV-2 claim for its OraQuick [®] Rapid HIV-1 Antibody Test.
99.2	Press Release dated December 17, 2003, announcing that the FDA has successfully completed a facility inspection required for the transfer of the Company's in-house and third party contract manufacturing operations from Oregon to Bethlehem, Pennsylvania.

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: December 18, 2003

By:

/s/ Jack E. Jerrett

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

Index to Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated December 15, 2003, announcing that the Company has submitted the additional data requested by the FDA in support of an HIV-2 claim for its OraQuick® Rapid HIV-1 Antibody Test.
99.2	Press Release dated December 17, 2003, announcing that the FDA has successfully completed a facility inspection required for the transfer of the Company's in-house and third party contract manufacturing operations from Oregon to Bethlehem, Pennsylvania.