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ORASURE TECHNOLOGIES INC

Form 8-K

January 31, 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): January 31, 2003

OraSure Technologies, Inc.

(Exact name of issuer as specified in charter)

DELAWARE
(State or Other
Jurisdiction
of Incorporation or
Organization)

1-10492
(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.

OraSure Technologies, Inc. (the "Company") issued a press release on January 31, 2003, announcing that it had submitted an application to the U.S. Food and Drug Administration (the "FDA") for a waiver under the Clinical Laboratory Improvements Amendments of 1988 ("CLIA") for the Company's OraQuick(R) Rapid HIV-1 Antibody Test (the "OraQuick(R) Test"). A copy of the press release is attached to this Report as Exhibit 99.1 and is incorporated herein by reference.

The Company issued a second press release on January 31, 2003, announcing that the FDA has approved the Company's application for a CLIA waiver for the OraQuick(R) Test. A copy of the press release is attached to this Report as Exhibit 99.2 and is incorporated herein by reference.

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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: January 31, 2003

By: /s/ Jack E. Jerrett

Jack E. Jerrett
Vice President, General Counsel
and Secretary

EXHIBIT INDEX

Exhibit

- 99.1 Press Release issued January 31, 2003 by OraSure Technologies announcing that it has submitted an application to the U.S. Food and Drug Administration for a waiver under the Clinical Laboratory Improvements Amendments of 1988 ("CLIA") for the Company's OraQuick(R) Rapid HIV-1 Antibody Test.
- 99.2 Press Release issued January 31, 2003 by OraSure Technologies announcing that the U.S. Food and Drug Administration has approved a CLIA waiver for the Company's OraQuick(R) Rapid HIV-1 Antibody Test.