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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.  
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(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

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Jack E. Jerrett  
Vice President, General Counsel  
and Secretary

### EXHIBIT INDEX

#### Exhibit

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- 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.