Orasure gets approval to sell hepatitis C test in Europe

By Spencer Soper
Of The Morning Call

Bethlehem medical devicemaker Orasure Technologies Inc. said Tuesday it has received regulatory approval to sell its hepatitis C test — one of its key products in development — in the European Union.

The company received approval to affix a CE mark to its OraQuick Rapid HCV Antibody Test. This mark is needed to sell the test in 27 European countries, which Orasure said it expects to do in the first quarter of next year.

The test is among Orasure's biggest pending products. Orasure's leading product, the OraQuick HIV test, is sold to hospitals and clinics and can test blood or fluid on gums for HIV indicators.

Its hepatitis C test uses similar technology. Hepatitis C is five times more prevalent than HIV worldwide. Orasure also is seeking approval of the test from the U.S. Food and Drug Administration.

"We believe that the OraQuick Rapid HCV Antibody Test, with its ability to test using a simple oral fluid or finger-stick blood sample, will be a valuable tool in identifying more individuals infected with hepatitis C," said Douglas Michels, Orasure's chief executive officer.

The regulatory approval of the test "represents a significant achievement and major milestone for our company," he said.

The test uses an oral fluid or finger-stick blood sample to help diagnose people before their livers become damaged beyond repair from hepatitis, which shows no signs or symptoms in many undiagnosed cases.

Orasure stock jumped 10.5 percent for the day to $4.73 on news of the regulatory approval.

OraSure is collaborating with Merck & Co., based in Whitehouse Station, N.J., to develop and promote the test worldwide.

Orasure employs about 300 people, mostly in Bethlehem.

The Associated Press contributed to this story.

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