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FDA permits marketing of first diagnostic test for detection of prosthetic joint infections

24 May 2019 | News

The Synovasure Lateral Flow Test Kit detects proteins called human alpha defensins in the synovial fluid ofpatients with a total joint replacement in approximately 10 minutes.

The U.S. Food and Drug Administration permitted marketing of the Synovasure Lateral Flow Test Kit as an aid for the detection of periprosthetic joint infection (infection around a joint replacement) in the synovial (lubricant) fluid of patients being evaluated for revision surgery, which is surgery performed to replace or compensate for a failed implant.

"Prior to today's authorization, there were no FDA-authorized diagnostic tests specifically designed to help health care professionals determine whether the inflammation around a prosthetic joint was due to an infection or another cause," said Tim Stenzel, M.D., Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health. "With this test, health care professionals now have an additional option available to aid their clinical assessment as to whether the patient has an infection and requires revision surgery. Whereas before surgeons may have opted for surgery when the presence of an infection was unclear, with this test, they have more information and could potentially reduce patient risk by avoiding unnecessary revision operations for replacement joints."

Joint replacement is a surgical treatment option for people with severe joint damage, including the knees or hips. During a joint replacement surgery, the surgeon removes damaged cartilage and bone from the surface of the joint and replaces it with a prosthetic joint implant. Potential complications of joint replacement include scarring, inflammation, blood clots and infections. If an infection occurs, it can lead to pain, redness, swelling and decreased joint function and potentially require antibiotics and revision surgery to treat the infection and install a new prosthetic implant. Physicians typically evaluate for potential infections using X-ray images or laboratory analysis of joint fluid, which can take days for results.

The Synovasure Lateral Flow Test Kit detects proteins called human alpha defensins in the synovial fluid of patients with a total joint replacement in approximately 10 minutes. Alpha defensins are antimicrobial proteins released by activated

neutrophils (white blood cells) in response to infection. The Synovasure Lateral Flow Test Kit is intended as an aid to determine whether there is an infection present in synovial fluid. It is not intended to identify a specific type of infection. The test results are also intended to be used in conjunction with other clinical and diagnostic findings to aid in a patient's diagnosis of prosthetic joint infection.

The FDA reviewed data from a clinical study that analyzed 305 prospective synovial fluid samples collected from individuals with a total knee or hip joint replacement who were being evaluated for revision surgery. The study showed that 89.5% of subjects with an infection diagnosis based on standard of care criteria were also identified as positive for alpha defensin by the Synovasure Lateral Flow Test Kit.

The FDA reviewed data for the Synovasure Lateral Flow Test Kit through the de novo premarket review pathway, a regulatory pathway for low-to-moderate-risk devices of a new type. Along with this authorization, the FDA is establishing criteria, called special controls, which determine the requirements for demonstrating the safety and effectiveness of tests to detect and measure non-microbial analytes (substances) that aid in the detection and identification of localized human infections. These special controls, when met along with general controls, provide a reasonable assurance of safety and effectiveness for these tests.

The FDA granted marketing authorization of the Synovasure Lateral Flow Test Kit to CD Diagnostics Inc.