First Home Test for Three Different STIs

The test is authorized only for women.

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The Food and Drug Administration (FDA) granted marketing authorization in March to Visby Medical for the Visby Medical Women's Sexual Health Test. This is the first diagnostic test for chlamydia, gonorrhea and trichomoniasis that can be purchased without a prescription and performed entirely at home. The test is intended for females with or without symptoms and delivers results in approximately 30 minutes.

According to the Centers for Disease Control and Prevention's (CDC) Sexually Transmitted Infections (STI) Surveillance Report, more than 2.2 million cases of chlamydia and gonorrhea were diagnosed and reported in the United States in 2023.

Additionally, it is estimated that trichomoniasis is the most prevalent nonviral STI worldwide, affecting about 2.6 million people in the United States, according to the CDC's treatment guidelines. Typically, all three infections can be treated with antibiotics, but if left untreated, they can cause serious health complications, including infertility.

The Visby Medical Women's Sexual Health Test is a single-use at-home test that includes a self-collection kit (vaginal swab) and a powered testing device, which communicates securely to the Visby Medical App, which displays results when the test is complete.

The FDA reviewed this test under the FDA's De Novo premarket review pathway, a regulatory pathway for low- to moderate-risk devices of a new type. Along with this De Novo authorization, the FDA is establishing special controls that define the requirements related to labeling and performance testing. When met, the special controls, in combination with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type.

This action creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through FDA's 510(k) premarket notification process, whereby devices can obtain marketing authorization by demonstrating substantial

equivalence to a predicate device, which may save a developer time and expense compared to other review pathways.

This announcement follows last year’s authorization of the first at-home syphilis test as well as the authorization of the first diagnostic test for chlamydia and gonorrhea with at-home sample collection in 2023, which was the first FDA-authorized test with at-home sample collection for any sexually transmitted infection other than HIV.
