Inito Provides Clarification Regarding Regulatory Status of its Hormone Level Diagnostic Test

SAN FRANCISCO, CALIFORNIA, UNITED STATES, June 23, 2023 /EINPresswire.com/ -- Inito has received recent inquiries about the regulatory classification of its Inito Fertility Monitor in the United States, and has noted confusion relating to specific statements in various media about Inito being “FDA-registered.” Specifically, the company noted that certain promotional materials had focused on the pathway by which the product is marketed in the United States.

To avoid confusion, the company is reiterating that Inito has listed the Inito Fertility Monitor with the U.S. Food and Drug Administration (FDA) as a Class I medical device that is exempt from FDA’s premarket notification submission requirements. As a class I exempt device, FDA clearance or approval is not required; the device has not been cleared or approved by FDA. Any statement relating to the company's registration status should not be misunderstood as suggesting that any Inito product has been reviewed, cleared, or approved by FDA.

The Inito Fertility Monitor is intended to monitor a woman's ovulation cycle by identifying the levels of estrogen, luteinizing hormone (LH), follicle-stimulating hormone (FSH), and pregnanediol glucuronide (PdG). The company would like to clarify that some of its earlier marketing materials used the words Progesterone and PdG interchangeably, and we apologize for any confusion this may have caused. In fact, the test measures PdG, which is the urine metabolite of progesterone; its levels also rise after ovulation.

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we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.