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Miris Human Milk Analyzer gets FDA nod to market

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The test provides healthcare professionals with a new tool to aid in the nutritional management of newborns and young infants at risk for growth failure due to prematurity or other medical conditions.

USFDA permitted marketing of the Miris Human Milk Analyzer, a new diagnostic test to aid healthcare professionals in measuring nutrients in breast milk, including the concentration of fat, carbohydrate, protein, total solids and energy.

The test provides healthcare professionals with a new tool to aid in the nutritional management of newborns and young infants at risk for growth failure due to prematurity or other medical conditions.

Some infants who are born prematurely or with health conditions may have special nutritional needs. Breast milk composition can vary in individuals, and, in certain cases, breast milk may not contain sufficient protein and energy levels for these infants with increased nutrient needs.

In those instances, healthcare professionals may want to test the nutrient content of the milk to help guide nutritional care. Knowing the macronutrient content of the breast milk may help the health care team and parents make informed decisions on how to fortify the breast milk based on the individual needs of the infant.

The Miris Human Milk Analyzer uses an infrared spectroscopy system to analyze samples of human milk and provide a quantitative measurement of fat, protein and total carbohydrate content as well as calculations of the total solids and energy content contained in the milk. This is a prescription device intended for use by trained health care personnel at clinical laboratories.

Health care professionals should carefully evaluate the Miris Human Milk Analyzer test results in conjunction with clinical assessments (such as weight and growth) to inform their discussions with parents in creating a nutritional management plan for an infant or newborn.

The FDA reviewed the Miris Human Milk Analyzer test 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, to provide for the accuracy and reliability of tests intended to measure the nutritional content of human milk to aid in the nutritional management of certain infants.

These special controls, when met along with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action also creates a new regulatory classification, which means that subsequent devices of the same type, including the same intended use, may go through the FDA's 510(k) process, whereby devices can obtain marketing authorization by demonstrating substantial equivalence to a predicate device.