

Press release

April 13th, 2023

AlgoDx announces FDA acceptance of De Novo application for the first ICU sepsis prediction algorithm.

AlgoDx announces today that the US Food and Drug Administration has accepted for review the company's De Novo application for NAVOY[®] Sepsis, a clinical decision support software intended to assist healthcare providers at intensive care units (ICU) with predicting sepsis in adult ICU patients.

- We are proud to announce that our software NAVOY[®] has been accepted by the FDA for substantive review through the De Novo classification process, which confirms the status of NAVOY[®] as the first such product in line to attain FDA clearance. We are looking forward to collaborating with the FDA throughout this process, says Andreas Macura, Chief Product Officer and QA at AlgoDx.

NAVOY[®] is a prediction algorithm software based on machine learning that accurately predicts the risk of ICU patients in developing sepsis the coming hours. NAVOY[®] has been clinically validated in the largest randomized clinical trial ever conducted with a sepsis prediction algorithm, and the software is approved for commercial use in the EU. AlgoDx's solution lies in the deployment of a machine learning-based prediction algorithm that, using only parameters that are routinely collected in high-acuity clinical information systems and electronic healthcare records. As such, NAVOY[®] autonomously and continuously predicts sepsis risk in ICU patients to assist healthcare provider with early sepsis detection.

- This is a major milestone for us, as we continue to support ICU providers in the US by delivering value-based care through integrated solutions that support providers in detecting sepsis in a timely manner, says David Becedas, CEO. A positive outcome from the FDA will differentiate our clinical decision support software from non-vetted products, continues David Becedas.

About sepsis and sepsis prediction

Sepsis can lead to multiple organ damage and is potentially life-threatening when the body's response to fight an infection is out of balance. Sepsis affects more than 30 million people worldwide annually and is responsible for around 6 million deaths. In cases of sepsis, timely initiation of treatment is crucial. The key components of effective intervention include the prompt and appropriate use of antibiotics, source control measures, and fluid administration. Current detection methods for sepsis are incapable of early prediction.

About AlgoDx

AlgoDx is a commercial stage medical device software company bringing value-based care for ICUs using integrated solutions. The company commercializes a portfolio of novel ML algorithms that can predict disease or worsening of disease in the ICU.

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