PRESS RELEASE
18 August 2022 07:55:00 CEST

Senzimes receives FDA 510k-clearance for a new disposable sensor intended for monitoring of children

Press release: Uppsala, August 18, 2022. Senzime today announces that the company's TetraGraph® -system has now received FDA 510k-clearance for use in children with the disposable sensor TetraSens Pediatric. Senzime can thus broaden the indication for TetraGraph to also monitor infants and young children who have received muscle paralyzing drugs as part of anesthesia.

Senzime's system for monitoring neuromuscular blockade during and after surgery - TetraGraph – is FDA cleared since 2019 and is currently sold in 29 countries worldwide. The market introduction of the small and flexible TetraSens Pediatric sensor will broaden the target patient group for the TetraGraph system to include the pediatric population from infants and up.

Studies show that children face the same risk of complications from the use of paralyzing drugs as adults[1]. Infants and children have also shown large variations and prolonged duration of action after administration of NMB. [2],[3]

Pia Renaudin, CEO at Senzime, comments: *"The use of paralyzing drugs in children is steadily increasing. Children are an extra sensitive patient group where it is important to monitor neuromuscular activity during surgery. Senzime continues to lead the market and launch innovative solutions that increase patient safety. Our new disposable sensor TetraSens Pediatric creates completely new conditions for monitoring neuromuscular blockade of children during and after surgery."*

[1] J Klucka et al, *Residual neuromuscular block in paediatric anaesthesia*, BJA 2019
[2] Debra J. Faulk, MD, *A Survey of the Society for Pediatric Anesthesia on the Use, Monitoring, and Antagonism ofNeuromuscular Blockade*, Anesthesia and Analgesia 2021
[3] Luc E. Vanlinthout et al, *Neurophysiological Assessment of Prolonged Recovery From Neuromuscular Blockade in theNeonatal Intensive Care Unit*

For further information, please contact:

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About Senzime

Senzime is a Swedish medical device company that develops, manufactures, and markets CE- and FDA-cleared patient monitoring systems. Senzime's employees worldwide are committed to the vision of a world without anesthesia- and respiratory-related complications. The company markets an innovative portfolio of solutions, including the TetraGraph® and ExSpiron® 2Xi for real-time monitoring of neuromuscular and respiratory functions, typically under and after surgery. The goal is to help eliminate in-hospital complications, and radically reduce health care costs related to surgical and high acuity procedures.

Senzime targets a market opportunity valued more than SEK 40 billion per year, and operates with sales teams in the world's leading markets. The company's shares are listed on Nasdaq Stockholm Main Market (SEZI). **www.senzime.com**

This information is information that Senzime is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2022-08-18 07:55 CEST.

Attachments

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