

OrNim cerebral oxygen monitoring device wins FDA approval

OrNim president and VP R&D Dr. Revital Shechter: The device is applicable for kidneys and muscles, and we'll return to the fetal market later.

Gali Weinreb 18 Mar 08 13:15

[OrNim Medical Ltd.](#) has obtained US Food and Drug Administration (FDA) approval for its non-invasive device for measuring oxygen levels in the brain. This is a critical measurement for patients with head trauma or undergoing general anesthesia during surgery. The current method for measuring cerebral oxygen levels is to insert electrodes through the skull, a procedure that OrNim's device supersedes. The company had filed a 510K abbreviated procedure application with the FDA.

OrNim co-founders, CEO and CTO Dr. Michal Balberg and president and VP R&D Dr. Revital Shechter were originally seeking a way to measure oxygen levels in fetuses, but quickly realized the cerebral applications of their device since the fetal market was too small for venture capitalists and the regulatory procedures for a fetal product were protracted.

Shechter said, "We sought a different sector where we could apply the same technology. We discovered a number of painful sectors. The first was measuring cerebral oxygen levels, but the product is also applicable for muscles and kidneys. When we become more established, we'll return to the fetal market."

OrNim's Ultrasound Tagged Light technology - UTLight, transmits a beam of light through tissue to measure the absorption of light by oxygenated and deoxygenated hemoglobin. The system tags the light with ultrasound beams enabling to bypass superficial tissue, and measure absolute oxygen saturation levels within the monitored tissue.

Shechter explains, "If the blood in the area marked by the ultrasound is red and oxygen-rich, it absorbs more tagged light. If the area is light and oxygen-poor, more tagged light is reflected back to us. In this way, we can precisely measure oxygen levels."

OrNim was founded in 2004, and raised capital from [Gilo Ventures](#), backed by Davidi Gilo, shortly afterwards. Shechter said, "Gilo isn't known in Israel as an investor in biomedical ventures, but he already had two previous investments in this sector, one of which was in an imaging company."

OrNim has raised \$3 million to date, and is now trying to raise \$7 million, of which \$2 million has already been secured from Gilo Ventures and private investors. The company already has EU CE Mark certification for UTlight, and plans to begin marketing in 2009, after conducting clinical trials on head trauma patients.

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