US FDA Grants 510(k) Clearance for Monitor Mask Respiratory Device

Firm's M1 Capnography Mask obtains US market authorization with support from Emergo Group.

Seattle based Monitor Mask Inc., has obtained US Food and Drug Administration 510(k) premarket notification clearance for the M1 Capnography Mask.

The M1 Capnography Mask is a disposable oxygen face mask designed to monitor patient breathing by directly interfacing with a sidestream capnograph. Capnography, or exhaled CO2 monitoring, is increasingly recognized as a safety enhancing modality for patients undergoing procedural sedation and for certain high risk hospitalized populations. With the M1 Capnography Mask, Monitor Mask seeks to facilitate the use of capnography and promote patient safety throughout healthcare.

Monitor Mask undertook its FDA 510(k) registration effort with support from Emergo Group, a medical device regulatory consultancy based in Austin, Texas. Dr. J. W. Beard, Founder and CEO at Monitor Mask, explains that his firm's partnership with Emergo Group was essential for a timely and efficient regulatory review of the M1 Capnography Mask.

"FDA clearance for access to the US market was a critical milestone for our business that we approached by weighing the trade-off of time and working capital," says Beard. "In our case, market timing was critical, so we chose to invest our resources to partner with Emergo Group to maximize our chances at an efficient regulatory process. The investment paid off."

According to Beard and Stuart Goldman, Senior QA/RA Consultant at Emergo Group, the two firms collaborated on refining Monitor Mask's business strategy, assembling necessary regulatory documentation and peer review of the manufacturer's 510(k) application before submission to the FDA.

"When it comes to FDA 510(k) registration, getting it right the first time can be crucial for medical device companies launching new products," says Goldman. "By enlisting us to support their application for FDA 510(k) premarket notification, Monitor Mask was able to commercialize the M1 Capnography Mask for sale in the US without any costly missteps."

About Emergo Group
Emergo Group is a medical device regulatory affairs and quality assurance consulting firm. Emergo Group provides services for worldwide device registration, quality management system implementation, and authorized representation throughout North and South America, Europe, Asia, Australia and the Middle East. Offices worldwide.
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