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QUOTED. Nov. 9, 2018. Pete DeComo.

by

When ALung Technologies was selected in 2015 by US FDA to participate in the agency's Expedited Access Pathway program for its novel *Hemolung* device, the firm wasn't necessarily sure what it was getting itself into. See what ALung CEO Pete DeComo said about the pathway – now called the Breakthrough Devices Program – here.

"For the FDA and ALung, it was, 'We're not sure about this, how is this going to work?' We would sometimes ask the FDA, and they would say, 'We don't know, we're going to work through it with you.' But I think we've gotten to a comfort level with that in terms of our working relationship with the FDA, which has learned along the way and has modified things within its program." –Pete DeComo, CEO, ALung Technologies Inc.

• Find out more: <u>Breathing Easy: ALung CEO Talks Novel Hemolung Device, FDA's Breakthrough</u> <u>Pathway, Landmark US/UK Clinical Trials</u>

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