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'Thinking Ahead': Shook Hardy Attorney Gets Quick FDA OK to Switch Apnea Devices to Ventilators

A small Florida company happened to make the right things at the right time during the coronavirus pandemic. But it needed help from its regulatory counsel at Shook Hardy to allow its apnea devices to be used as noninvasive ventilators.

by Catherine Wilson

A Winter Haven company wanted to switch its sleep apnea machines to ventilators to help fight COVID-19 but needed special permission from the Food and Drug Administration.

Shook, Hardy & Bacon's Sonali P. Gunawardhana in Washington came to the company's rescue.

While 3B Medical Inc. wanted to respond a World Health Organization directive, its machines weren't made or licensed for use in the United States, company CEO Alex Lucio said Friday.

Gunawardhana, a 10-year veteran of the Food and Drug Administration, fast-tracked emergency applications to quickly get the positive airway pressure devices, called Luna G3 BPAP ST, to U.S. health care providers for use as non-invasive ventilators.

The applications went in March 24, the FDA issued guidance to device makers interested in converting devices to ventilators a short time later, and the approval landed at 9:43 p.m. April 2 to allow shipping the next day.

The only notable change to the product was adding instructions to switch the machine's operations from intermittent flow for people with apnea to continuous flow for the coronavirus patients with severe lung infections.

Courtesy photo

Sonali P. Gunawardhana Of counsel with Shook, Hardy & Bacon, in Washington.

"These people were innovative enough to come up with these products, really

thinking ahead, and they weren't planning on using it for this, but they had other things in mind," Gunawardhana said.

The FDA opened the door to innovation during the coronavirus pandemic by issuing a short-term emergency authorization covering the unspecified time until it declares the COVID-19 emergency is over.

"They have done them in the past when these things come up, but I feel like this is way larger," Gunawardhana said, citing other authorizations over the years covering Ebola, SARS, MERS and anthrax.

In 3B Medical's case, a Chinese manufacturer builds a microprocessor-controlled system that has sales authorization and is used widely in EU countries under a CE mark. That's short for conformite europeenne, a French phrase used on products certified to meet European health, safety and environmental protection standards.

FDA approval was needed before U.S. customs workers would clear shipments to the United States. The company had 2,000 devices ready for delivery and is capable of making 10,000 a month. From mid-March to early April, media reports of ventilators in the national stockpile ranged from about 4,000 to 10,000.

The FDA is "trying to assist in every way possible with getting products out to the field, just alternatives due to this dire need for ventilators," she said. "They have worked just as quickly as they can. I talk to them late at night. Everybody is working."

Lucio has high praise for Gunawardhana, saying, "She is amazing. I love her to death."

With Shook Hardy serving as the company's FDA counsel, he credited Gunawardhana with spearheading the regulatory approach, saying, "She was able to get us visibility at a very high level."

With 3B Medical operating an essential business in the pandemic, the 9-year-old company he co-founded is busier than ever.

"I've been kind of of running straight 24/7 with very little sleep. The whole world has gone crazy," Lucio said. "This is a challenge, and we should step up to meet it. It does feel really good to have products that can save lives and make a difference, so there's a lot of satisfaction in that."

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