

FDA OKs breathing device used by Christopher Reeve

By M.R. KROPKO – 19 hours ago

CLEVELAND (AP) — The Food and Drug Administration on Wednesday approved a medical device tested about five years ago on actor Christopher Reeve to help him breathe without a ventilator.

The implantable device, called NeuRx DPS RA/4 Respiratory Stimulation System and developed by Synapse Biomedical Inc. of Oberlin, Ohio, electrically stimulates the muscles and nerves that run through the diaphragm. It allows some spinal cord injury patients to breathe for at least four hours a day without a mechanical ventilator.

Reeve was paralyzed from the neck down in a horseback riding accident in 1995. The "Superman" star received the experimental device in 2003, allowing him to breathe off a ventilator for about 15 minutes.

Reeve later used it eight hours at a time and eventually was able to go up to 20 hours off a ventilator, said Synapse president and CEO Anthony Ignagni. Reeve died in 2004 after developing a bloodstream infection from a bedsore.

The device does not cure paralysis of the diaphragm, but getting patients to be free from a ventilator may enhance their quality of life, said Dr. Daniel Schultz, director of the FDA's Center for Devices and Radiological Health.

Spinal cord injuries can affect the muscles of the chest and abdomen, including the diaphragm, which is a lower abdominal muscle essential for breathing.

Normally, a person inhales when the diaphragm contracts and the lungs expand with air, and a person exhales when the diaphragm relaxes and the air flows back out of the lungs.

The stimulation device uses four electrodes implanted in the muscle of the diaphragm to stimulate contraction.

The FDA approved the distribution of the stimulation system under a Humanitarian Device Exemption, an approval process for unique medical devices intended to treat or diagnose conditions that affect fewer than 4,000 people per year.

"Fortunately, there's not a lot of ventilator-dependent spinal cord injuries in the U.S., about 500 per year," Ignagni said.

He said Synapse is trying to expand application of the device to patients with amyotrophic lateral sclerosis, also known as Lou Gehrig's disease, which can shut down muscular function and inhibit breathing.

Dr. Raymond Onders, director of minimally invasive surgery at University Hospitals Case Medical Center in Cleveland, performed surgery to implant the stimulation device into Reeve. He said Reeve helped draw public attention to the technology because of his fame and willingness to try an experimental treatment. Onders helped form Synapse in 2002.

"His operation took several hours. We've fine-tuned it to where it's become a 30-minute outpatient procedure," Onders said.

The FDA approval is based on treatment results on 50 patients implanted with the device in clinical trials at hospitals in the U.S. and Canada.

Those include University Hospitals Case Medical Center in Cleveland, Shepherd Center in Atlanta, The Methodist Hospital in Houston and Vancouver General Hospital in Vancouver.