Remede system approved for sleep apnea

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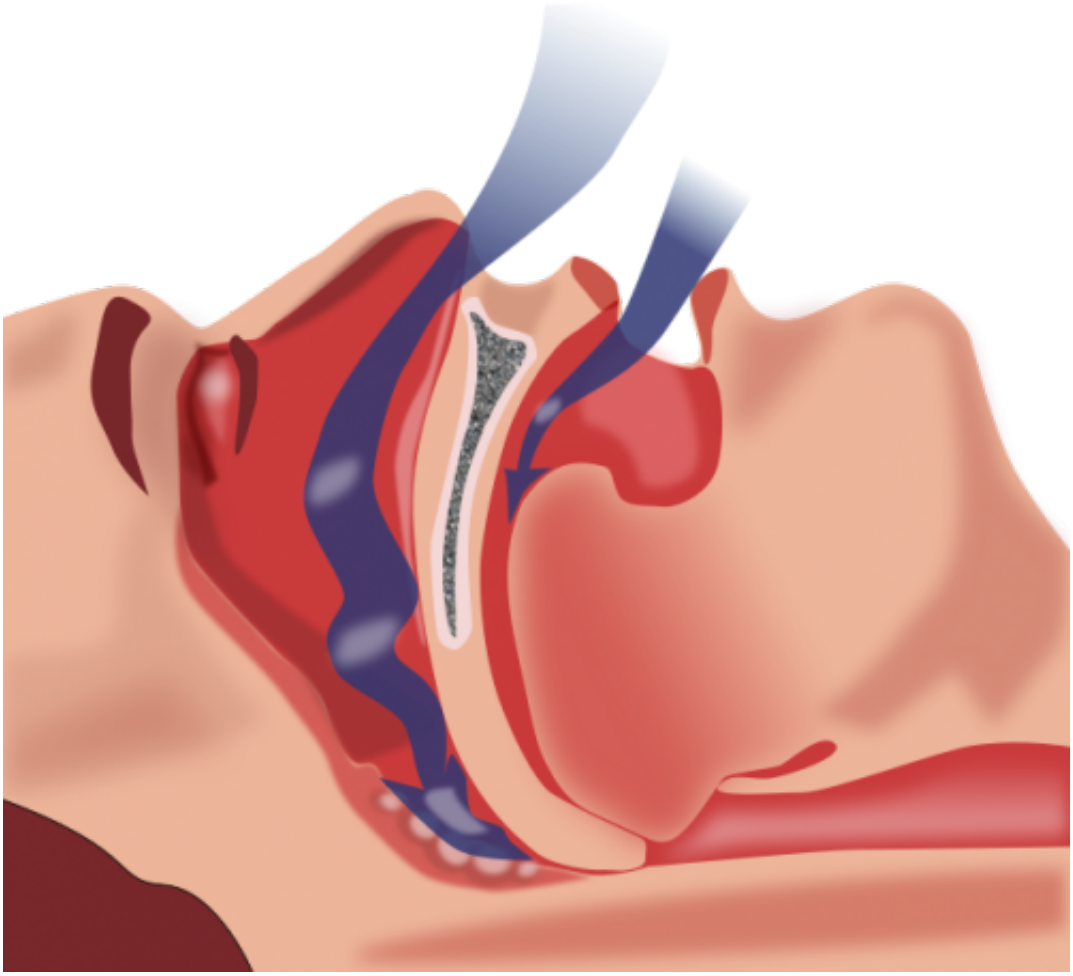

Illustration of obstruction of ventilation. Credit: Habib M'henni / public domain

(HealthDay)—The Remede sleep system, an implanted device that treats central sleep apnea by activating a nerve that sends signals to the

diaphragm to stimulate breathing, has been approved by the U.S. Food and Drug Administration.

Central sleep apnea occurs when the brain fails to send signals to the diaphragm, triggering lapses in breathing that can last a few seconds to minutes, the agency said in a news release. This can lead to poor sleep and ultimately raise a person's risk of health problems such as high blood pressure, heart attack, heart failure, stroke, obesity and diabetes, the FDA said.

The condition is different from the more common obstructive sleep apnea, in which breathing disruptions are caused by upper airway obstruction.

"Patients should speak with their health care providers about the benefits and risks of this new treatment option compared to other available treatments," said Tina Kiang, acting director of the FDA's Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices.

Common treatments for sleep apnea include medication, positive airway pressure devices or surgery, the agency said.

The new system, including a battery pack implanted in the chest, stimulates the phrenic nerve and monitors a person's lung function during sleep, the FDA said. In clinical testing involving more than 140 people, a measure of sleep apnea was reduced by at least half among 51 percent of people who used the system. That compared to an 11 percent reduction among those who didn't have the system implanted.

The most common adverse reactions included implant-site infection and swelling near the implant site. The system should not be implanted in people with an active infection or among people who require use of an

MRI machine, the FDA said.

The system is produced by Respicardia Inc., based in Minnetonka, Minn.

More information: Visit the FDA to learn more.