FDA says repaired sleep apnea machines still carry health risks

April 10 2023, by Cara Murez

The U.S. Food and Drug Administration has issued another warning

about certain sleep apnea machines made by Philips Respironics.

Already the subject of a 2021 recall, some of the company's repaired continuous positive airway pressure (CPAP) machines may still be dangerous to use, the agency said in an alert issued Friday.

"The FDA has identified this as a Class I recall, the most serious type of recall," the agency said. "Use of these devices may cause serious injuries or death."

The original problem with some of the machines was that foam that is meant to dull noise was breaking off from inside the machine and going into the mouths of people using the unit for sleep apnea. Inhaling the foam can cause "serious injury, which can be life-threatening," Philips noted in its original recall notice.

The latest issue with some of the machines is that the company gave repaired machines the wrong or duplicate serial numbers, the latest FDA alert said. That may lead to the devices delivering the wrong prescription to sleep apnea patients. If receiving the wrong prescription, patients may not receive any CPAP benefits.

"Incorrect therapy or therapy failure may lead several health conditions such as respiratory failure, heart failure, serious injury and death," the FDA added.

Philips' Friday statement acknowledged the repair issues, including that a "limited amount [1,200] of remediated first-generation DreamStation CPAP devices had been incorrectly programmed with either an incorrect serial number or a duplicate serial number."

The company is notifying patients if their machines may provide them with the wrong prescriptions.

"To date, we are more than halfway with the shipments of replacement devices to patients," the company said.

The FDA has tracked complaints numbering 98,000 since the 2021 recall. People have reported having respiratory problems, pneumonia, dizziness, chest pain, infections and cancer.

In addition, the company has been sued by dozens of sleep apnea patients, *CBS News* reported.

The company said it has received 43 complaints about the repaired machines. No one has reported injury or death.

Sleep apnea affects about 30 million Americans. It causes blocked airways during rest and interrupts breathing.

More than 20 different Philips devices have been recalled, including the A-Series BiPAP ventilators, the DreamStation CPAP machines and the Trilogy 100 and 200 style ventilators.

More information: The U.S. National Institutes of Health has more on sleep apnea.