

Owlet baby socks discontinued after FDA warning. Parents argue device offers 'peace of mind'

November 30 2021, by Gabriela Miranda



Credit: Anna Langova/public domain

Owlet's Smart Socks, baby monitoring socks programmed to track a baby's sleep patterns, have halted sales after a warning letter from the U.S. Food and Drug Administration.

The FDA stated the socks were [medical devices](#) since they provide [heart](#)

[rate](#) and [oxygen levels](#) but Owlet claimed the smart socks were "low-risk products." In the [warning letter](#), the FDA said the company has sold the product without proper "marketing approval, clearance, or authorization" from the FDA.

As of Tuesday morning, the Owlet Sock family of products is "currently unavailable," according to the Smart Socks' product page, and thousands of [parents](#) are unhappy.

"Keeping this product on the market would ensure peace of mind for millions of parents and quite literally save lives by alerting parents to an issue before it's too late," Caitlin Needham said in her [petition](#) to keep the Smart Sock.

The petition has garnered over 150,000 signatures of concerned parents who say the Smart Socks give them "peace of mind."

One night while Needham was nursing her newborn, she fell asleep. She stayed asleep until her she heard her daughter's Smart Sock alert go off and realized her child was pressed against her side and underneath her breast.

"I can't say for sure what would have happened had the monitor not gone off but I'm thankful it did. This is a product that has given peace of mind to millions of parents," Needham said in the petition.

Marny Smith, who also signed the petition, is a mother of three and told U.S. TODAY without the Smart Sock she'd lose her "mental health" while nursing and caring for her children.

"The FDA is going after the device, the Smart Sock is so necessary for parents now. It's the only way I can sleep and know my child is okay," Smith said.

Kelli Stout signed the petition and commented the device lead doctors to discovering her child had sleep apnea.

Since 2016, the FDA has contacted Owlet about altering their marketing of the baby monitoring socks, according to the letter. In response to the FDA, Owlet posted their own letter on its site, explaining they plan to comply with the agency's request and seek marketing approval going forward.

Owlet pointed out the FDA didn't "identify any safety concerns about the Smart Sock," and claimed the safety of the socks had "been validated by third parties, in which it was shown to be safe."

When questioned on whether customers can continue using the Smart Socks, the company said "the product's functionality has not changed at this time. We will notify customers of any updates to the Smart Sock products that have already been distributed."

"We're all signing the petition with one goal in mind, to save the Smart Sock so it can one day save another parent from a headache or lack of sanity," Smith said.

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