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QUOTED. Owlet Baby Care Inc.

by

Owlet Baby Care has stopped selling its Smart Sock baby monitoring device after a five-year fight with the US Food and Drug Administration over whether the product should be regulated as a medical device. The company is now seeking FDA clearance.

“The letter we received from the agency did not identify any safety concerns about the Smart Sock; rather, the FDA asserts that the Smart Sock should be classified as a medical device in the US because of the heart rate and oxygen notifications.” – Owlet Baby Care Inc.

- Find out more: [FDA Warning Letter Prompts Company To Stop Selling Baby-Monitoring Device](#)

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