

Recently, The Jackson Walsh Foundation, in keeping with its mission embarked on a program intended to donate Owlet Smart Socks to families in need but lacked the means to afford the Socks. According to Owlet, a leading manufacturer of baby wearables,

*'this smart baby monitor helps you know your baby is okay by using proven technology to track their heart rate and oxygen levels. The Smart Sock sends this information to a base station which is designed to notify you with lights and sounds if something appears to be wrong. Using Owlet's app, you can view real-time wellness data and receive direct notifications on your phone. Parents who use the Owlet Smart Sock report better sleep and less worry. All new moms and dads can use peace of mind and a little extra help with baby while they sleep. The Smart Sock can help by keeping them informed of what matters most, making it the perfect baby shower gift for expecting moms and dads.*

*The Smart Sock is an information-gathering product intended to assist in tracking the well-being of healthy babies from 6 to 25 pounds and up to 18 months of age. Sizing is a guideline only and does not guarantee fit. It is not a medical monitor or other medical device and is not intended to diagnose, cure, treat, alleviate or prevent any disease or health condition or investigate, replace or modify anatomy or any physiological process. You should always follow pediatrician-recommended safe sleep practices when using the Smart Sock. Since baby skin is soft, sensitive and can be quite hydrated, if the sock is on one foot throughout the night, it is possible for the following to occur: an indentation can develop in that area, a "water bubble" can develop in the area, and/or redness around the circumference of the ankle or along the side of the foot can occur. To prevent these issues, do the following: check that the size of the sock is not too big or too small, ensure baby's foot is clean and dry before putting on the sock, and rotate which foot you put the sock on between uses. Constant movement can cause enough friction to create hot spots on their foot. If this occurs, rest the foot with the mark on it and don't put the sock back on that side until the mark has gone away.*

Owlet also provides the following Legal Disclaimer:

*Warning: The Smart Sock is not a medical device. It is not intended for use as a medical device or to replace a medical device. It does not and is not intended to diagnose, cure, treat, alleviate or prevent any disease or health condition or investigate, replace or modify anatomy or any physiological process. The Owlet Smart Sock is meant for healthy babies up to 18 months of age and the notification thresholds on the Owlet Smart Sock are not as stringent as a medical monitor. Remember: This product is only intended to assist you in tracking your baby's well-being and is not intended to replace you as a caregiver. You are responsible for the health and well-being of your baby and following safe sleep, health, and care guidelines. Do not use the Smart Sock as a diagnostic tool. Do not use the Smart Sock if your doctor recommends the use of a hospital pulse oximeter. Do not use the Smart Sock if your doctor recommends the use of a hospital apnea monitor. Do not use the Smart Sock as an excuse for unsafe sleep habits. Do not use the Smart Sock as a replacement for or in lieu of adult care.*

This past week we were made aware of the following actions:

1. The federal Food and Drug Administration (FDA) issued a warning letter on October 1<sup>st</sup> 2021 to Owlet Baby Care over its Smart Sock, a device that uses infrared light to monitor a baby's heart rate and blood oxygen level. In its letter, the FDA claimed Owlet's marketing of the Smart Sock rendered the product a medical device that would traditionally need premarket FDA clearance or approval, which Owlet does not have. The FDA has requested Owlet cease commercial distribution of the Smart Sock as a product intended for measuring blood oxygen saturation and pulse rate.
2. The American Academy of Pediatrics (AAP) recommends against using these high-tech baby monitors in healthy infants suggesting that there is no evidence the devices even work.

Owlet recently published the following response and Q&A on their website:

*Owlet received a Warning Letter from the FDA regarding the Smart Sock's regulatory status in the United States. 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 U.S. because of the heart rate and oxygen notifications. Based on the FDA's recent letter, Owlet plans to pursue marketing authorization from the FDA for these features.*

*As a result of the letter and in light of our plans to submit a device application to the FDA, we will no longer be selling the Smart Sock. We plan to offer a new sleep monitoring solution, which we believe will be available soon. We also plan to continue to support our current customers. There has not been any change to your product's functionality or a request from the FDA to exchange or return your product at this time. We will notify customers of any updates to the Smart Sock products that have already been distributed. This action is specific to the U.S. only and no other countries or regions are affected by this.*

*With over 1 million babies monitored, we are extremely proud of the innovation and technology Owlet has delivered. We will continue to stay focused on our mission and are cooperating with the FDA so we can continue to provide sleep monitoring products and solutions to parents and babies.*

***Can I continue using my Smart Sock?***

*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.*

***When will you hear back from the FDA?***

*We've responded to the FDA's Warning Letter and hope to meet with the agency soon, and we will share more information as we have it.*

***Is Owlet going to obtain FDA clearance to make the Smart Sock a medical device?***

*We plan to work toward the submission of a device application to FDA. We plan to meet with the FDA soon to reiterate our commitment to these efforts.*

***Is the product safe?***

*The Smart Sock's safety has been validated by third parties, in which it was shown to be safe. In addition, the letter we received from the agency did not identify any safety concern about the Smart Sock.*

***What if I have more questions?***

*Please contact our Customer Service team ([contact@owletcare.com](mailto:contact@owletcare.com) or 844-334-5330 in the U.S.).*

The Jackson Walsh Foundation's mission is to provide support for the education and protection of families regarding the issue of Sudden Unexpected Death Syndrome. We are not doctors nor medical researchers and we do not endorse any product. If you are interested and/or actively using Owlet Smart Socks, we recommend that you review the information we have posted here, and familiarize yourself with the issues raised by the FDA and the response provided by Owlet.

If you received an Owlet Smart Sock from us through our Program, The Jackson Walsh Foundation advises that you avoid using the Owlet Smart Socks that we provided until you have had the chance to review and understand the FDA's concern and Owlet's response to it. At that point, you can properly assess the risks and decide whether you want to continue using the Socks. If you wish to return the

Socks to us, we will be happy to accept a return. In keeping with our mission, we will do our best to keep the public informed.