

# Information on Baby Products with SIDS Prevention Claims

U.S. Food & Drug Administration

Some baby products are being marketed over-the-counter with claims to cure, treat, or prevent a disease or condition. Because of these claims, these baby products are medical devices, subject to FDA regulation.

A common medical claim being made is the prevention of Sudden Infant Death Syndrome (SIDS). The [National Institute of Child Health and Human Development](#) [1] defines SIDS as "the sudden death of an infant under one year of age, which remains unexplained after a thorough case investigation, including performance of a complete autopsy, examination of the death scene, and review of the clinical history."

**The FDA has never cleared or approved a baby product to prevent or reduce the risk of SIDS.** The Agency is not aware of any scientific studies showing that a medical device prevents or reduces the risk of SIDS.

Examples of common over-the-counter baby products with unproven claims to prevent or reduce the risk of SIDS include:

- baby monitors,
- mattresses,
- crib tents,
- pillows,
- crib bedding, including bumpers and blankets, and
- infant positioners.

Current research shows that the best way to reduce the chance of SIDS is to create a safe sleep environment for a baby: alone, in their own sleeping space with no other people in the crib or bassinet; on their backs on a firm sleep surface; and in a crib or bassinet free of pillows, blankets, bumpers, sleep positioners, and other objects.

The purpose of this website is to:

- help manufacturers of baby products understand and comply with the FDA laws and regulations for medical devices and
- educate parents and caregivers about the risks of using over-the-counter baby products marketed with SIDS medical claims.

[SOURCE](#) [2]

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### **Links:**

[1] <http://www.nichd.nih.gov/sids/>

[2] <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SIDSPreventionClaims/default.htm>