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K96-0747
Infant Advantage, Inc

16. 510(k) SUMMARY

The Nature's Cradle® Model C1500, when used as directed, is designed to provide a safe and effective transition to infants after birth, allowing them to grow accustomed to their new environment at a pace that minimizes stress. The mattress is equipped with motion and sound designed to simulate the mother's heartbeat and circulatory system familiar to the infant during the last trimester of pregnancy. Nature's Cradle® Model C1500 is intended to be used for healthy, full term infants at home from 0-16 weeks. The Nature's Cradle® Model C1500 is non-sterile and reusable.

The Nature's Cradle® Model C1500 is a new device that is based on the same technology and the same indications for use as Nature's Cradle® Infant Bassinet, Model M-1, 510(k) Premarket Notification # K901763. The moving platform is now embedded in the mattress, thus omitting the bassinet. The new mattress fits standard crib size (27 1/2 wide, 51 7/8" long, 4 1/2" high.) The sounds are fed to the mattress through a speaker cable from a control box located outside the mattress. The motions are generated by a low voltage DC (direct current) motor located underneath the platform and connected to a worm drive gear reduction located in the control module. Control module and moving platform are connected with a tube including speaker wire and power supply for the DC motor. Reliability testing shows this product to be as safe and effective as predicate device, Nature's Cradle® Model M-1, Premarket Notification # K901763.

The Nature's Cradle® Model C1500 has the same device classification product code (80FMS), the same technology and fundamentals of principles, and the same indications for use as the legally marketed, predicate device.

Laboratory and bench testing of Nature's Cradle® Model C1500 demonstrated that the new device performance is suitable for use in homes.

A clinical trial, published in the Journal of Perinatology Vol. 15, No. 3, 1995, involving 90 full term infants was performed at Kaiser Medical Center, Santa Clara, CA. The infants were evaluated utilizing the Brazelton Neonatal Behavior Assessment Scale. The study found that infants who sleep in the Nature's Cradle® environment were more adaptive, less irritable, and cried approximately 65% less. Additionally, they were more attentive, and alert, slept for longer periods, and slept through the night sooner, plus experienced a lower incidence of colic when compared to the control group.

16. 510(k) SUMMARY, continued

Clinical data submitted for predicate device, Model M-1, demonstrated that the device is safe and effective for use with healthy, full-term infants at home.

The device is available without a prescription, the same as predicate device, Nature's Cradle[®] infant bassinet, Model M-1, Premarket Notification # K901763.

The Nature's Cradle[®] Model C1500 uses the same software for motion and sound as predicate device, Model M-1, and uses the same control panel functions for motion and sound as predicate device, Model M-1. It also uses the same double-insulated transformer as proven safe and effective in predicate device Model M-1.

The labeling includes adequate warnings and cautions for safe and effective use of the product also have been incorporated in the product labeling.

Nature's Cradle[®] Model C1500 performs in the same manner as Model M-1. Manufacturing and testing of hardware and software remain unchanged to predicate device. The new device has proven safe and effective when used as directed.

Substantial equivalence to the legally marketed predicate device with the same indications for use has been demonstrated by comparison of product features, as described in 510(k) Premarket Notification # K901763 for Nature's Cradle[®] Model M-1, product labeling and promotional materials.