K062143

1 of 1

510(k) Summary

OCT 24 2006

Applicant Name:	Alfred E. Mann Institute for Biomedical Engineering at the University of Southern California
Address:	1042 W. 36th Place, DRB 101 Los Angeles, CA 90089
Contact Person:	Arman H. Nadershahi, Esq.
Telephone:	(213) 740-8271
Preparation Date:	July 24, 2006
Device Trade Name:	Kozy Comfort™ Infant Positioner
Device Common Name:	Infant Sleep Positioner
Classification Name:	Holder, Infant Positioner, Code FRP, CFR 880.5680
Class:	Class I
Predicate Device:	NightForm – 510(k) # K041996 Pedicraft Reflux Wedge – 510(k) # K905629
Device Description:	Kozy Comfort™ Infant Positioner is a polyurethane based infant positioner.
Intended Use:	The device is intended for positioning infants 0-12 months of age to prevent a condition known as deformational plagiocephaly.
Performance Summary:	FDA has not established special controls or performance standards for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2006

Mr. Arman H. Nadershahi
Head of Legal Affairs
Alfred E. Mann Institute for Biomedical Engineering
at the University of Southern California
1042 W. 36th Place, DRB 101
Los Angeles, California 90089

Re: K062143
Trade/Device Name: Kozy Comfort™ Infant Positioner
Regulation Number: 21 CFR 880.5680
Regulation Name: Pediatric Position Holder
Regulatory Class: I
Product Code: FRP
Dated: July 24, 2006
Received: July 27, 2006

Dear Mr. Nadershahi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

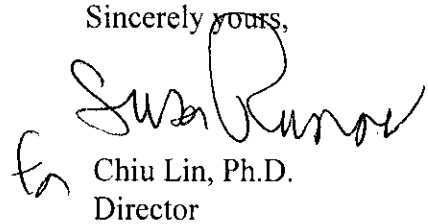
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K062143

Device Name: Kozy Comfort™ Infant Positioner

Indications For Use:

The Kozy Comfort product is indicated for healthy infants 0-12 months to aid in the prevention of skull deformities that may arise from consistent back-sleeping postures, namely the condition know as deformational (or positional) plagiocephaly

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...Sign-Off)
...ion of Anesthesiology, General Hospital,
...ion Control, Dental Devices

...) Number: K062143