K041996

Plastic Surgery Solutions, LLC

"Designer and marketer of NightForm infant positioning mattress."

1 of 2

AUG - 3 2004

A. APPLICANT INFORMATION

Submitter

Plastic Surgery Solutions, LLC
1150 N. 35th Avenue
Suite 490
Hollywood, FL 33021

Submitter Contact Information

Phil Carter
Phone: 954-648-6617
Fax: 509-463-2465

Submitter Registration Number (Owner/Operator): 9060469

Manufacturer:

JMB Products, Inc.
1401 Davey Road #750
Woodridge, IL 60517

Application date:

June 3, 2004

B. DEVICE NAME AND CLASSIFICATION

Common Name: Infant sleep positioner

Classification Name: Holder, Infant Position, Code FRP, CFR 880.5680

Trade Name: NightForm™

Class: Class I

Predicate Device:
The subject device is substantially equivalent to a predicate device ***Pedicraft Infant Reflux Wedge*** (K905629).

Device Description:
NightForm is a fabric-covered polyurethane foam mattress with two accompanying fabric-covered polyurethane wedges that affix to the mattress

by hook/loop fasteners in various positions that permit parents to modify nightly the supine sleeping position of their sleeping infants and thereby prevent a condition known as deformational plagiocephaly.

Intended Use:
The device is intended to be used preventatively during sleep for infants 0-9 months of age to prevent a condition known as deformational plagiocephaly.

Predicate Comparison

Comparison	NightForm™ Infant Sleep Positioner	Pedicraft Reflux Wedge K 905629
Application	Sleep positioning	Sleep positioning
Target Population	Infants 0-9 months	Infants
Purpose	To maintain the infant in sleep positions that prevent deformational plagiocpehaly.	To maintain the infant in a sleeping position which prevents gastro-esophogeal reflux.
Materials	Fire retardant foams, fire-retardant fabrics (treated cotton or poly/cotton blend), mechanical hook& loop fasteners, nylon zipper.	Foams, vinyl covering, fabric sling.

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

AUG - 3 2004

Plastic Surgery Solutions, LLC
C/O Mr. Ned Devine
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue SE
Grand Rapids, Michigan 49548

Re: K041996
Trade/Device Name: NightFormTM, Infant Sleep Positioner
Regulation Number: 880.5680
Regulation Name: Pediatric Position Holder
Regulatory Class: I
Product Code: FRP
Dated: July 22, 2004
Received: July 26, 2004

Dear Mr. Devine:

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.

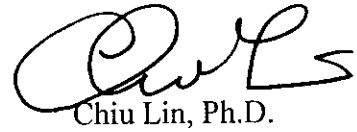
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618 . 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/dsma/dsmamain.html

Sincerely yours,



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

K041996

Indications for Use

510(k) Number (if known): K041996

Device Name: NightFormTM, Infant Sleep Positioner

Indications for Use:

The NightForm product is indicated for healthy infants 0-9 months to aid in the prevention of skull deformities that can rise from consistent back-sleeping postures, namely the condition known as deformational (or positional) plagiocephaly.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041996