

NOV 13 1997

Summary:

- **Submitter's name:** Cavity Free Kids
Address: 1224 Arcade St.
St. Paul, MN
Telephone: 612-774-0583
Fax Number: 612-793-0967
Contact person: Dr. Vacharee S. Peterson
Summary prepared: May 16, 1997

- **Trade Name:** Pedo Cush Pedo Cuddle

Common Name: Protective Restraint

Classification name: Protective Restraint (per 21 CFR 880.6760)

- **Identification of legally marketed device to which equivalency is claimed:** Olympic Papoose Board, manufactured by Olympic Medical Co. Seattle, WA.

Description of Pedo Cush Pedo Cuddle:

A combination restraint and cushion for securing a pediatric patient in a dental chair, said combination comprising: a restraint comprising a main body portion which has a plurality of flaps attached thereto, each of said flaps having hook and loop fasteners affixed thereto, such that said flaps can be positioned and fastened around said patient to hold said patients torso in position a plurality of strings (straps) for tying said restraint around said dental chair and a headpiece which fits around the top of said dental chair, said restraint having adhesive material affixed to the back thereof to hold said restraint in position on said dental chair; and a cushion having an arcuate indentation at its top end to hold said patient's buttocks in position, said cushion being enclosed in a pillowcase having an adhesive material affixed to the underside thereof in order to maintain said cushion in position on said dental chair, said pillowcase having a plurality of flaps attached thereto, said flaps each having hook and loop fasteners affixed thereto such that said flaps can be positioned and fastened around said patient's legs to hold them in position. Pedo Cush Pedo Cuddle is covered by U.S. Patent N. 5,425, 381 and is described in more detail therein.

Intended use:

To protect both patient and clinician from sudden and unsafe patient movement.

Comparison of technological characteristics:

	Pedo Cush	Pedo Cuddle	Papoose Board
Design		Wrap and Cushion, each having flaps with Velcro closures	Wrap with Velcro closures; board and head stabilizer can be added
Materials		Wrap (including flaps, straps, and headpiece) made of soft cloth with non-slip-rubber backing, has Velcro closures. Foam cushion enclosed in hospital ticking vinyl inserted in cotton outer jacket	Mesh fabric wrap with Velcro closures. Vinyl-covered board, plastic head stabilizer.
Performance		Controls side-to-side and up-and-down motion of patient in dental chair. Tested on over 1,000 child patients with behavior ranging from uncooperative and fearful to hysterically out-of-control; successfully managed the patients to allow dental procedures to be performed.	Controls side-to-side and up-and-down motion of patient in dental chair. Currently on market.
Sterility:		Jacket can be laundered and bleached.	Same
Safety:		Secures patient firmly and comfortable in dental chair.	Same
Anatomical sites:		Secures patient's torso and legs	Same
Human factors:		Comfortable and relaxing for patient	Same
Compatibility with other devices:		Can be used with any standard dental chair	Same
Where used:		Dental office	Same



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Vacharee S. Peterson
Cavity Free Kids, Incorporated
1224 Arcade Street
St. Paul, Minnesota 55106

NOV 13 1997

Re: K972446
Trade Name: Pedo Cush Pedo Cuddle
Regulatory Class: I
Product Code: FMQ
Dated: October 9, 1997
Received: October-14, 1997

Dear Dr. Peterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

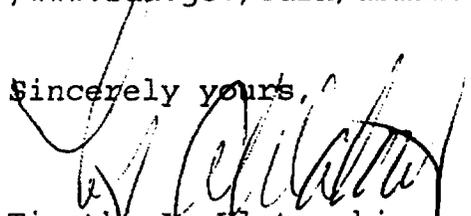
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 972446

Indications For Use

510(k) Number (if known) K972446

Device Name: PEDO CUSH PEDO CUDDLE

Indications For Use:

Pedo Cush Pedo Cuddle is to be used under the direction and/or the supervision of a dentist only, as a tool to help manage an uncontrollable child for the purpose of protection of the child from injury while receiving dental treatment. It is not to be used as a punishment tool. The Health Professional must be in control of his/hers emotions while using the Pedo Cush if at any time he/she feels the overwhelming of the emotions he/she must take a break, deliver the child back to the parent's arms. After the emotions are under control then he/she may continue to work. Remember that the option of referring out to another dentist is a possibility.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Ciccone

(Director Sign Off)

Division of Device, Infection Control,
and General Hospital Devices

510(k) Number K 972446

Prescription Use

OR

Over-The-Counter Use

(Optional Format 1-2-96)