

K972446

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 20860

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 pre-market notification submission does not affect any obligation you might have under sections 531

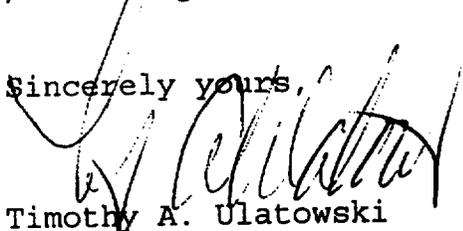
Page 2 - Dr. Peterson

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 Cicento

(Director Signature)
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)



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

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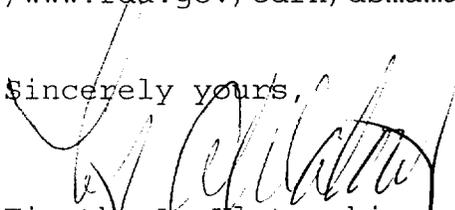
Page 2 - Dr. Peterson

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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

K972446

Indications For Use

510(k) Number (if known) K972446

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Ciccone

(Director Signature)
Division of Device Evaluation, Infection Control,
and General Hospital Devices

510(k) Number K 972446

Prescription Use

OR

Over-The-Counter Use

(Optional Format 1-2-96)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date: 11/13/97

From: Reviewer(s) - Name(s) Irene Naveau

Subject: 510(k) Number K972446/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review October 17, 1997
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

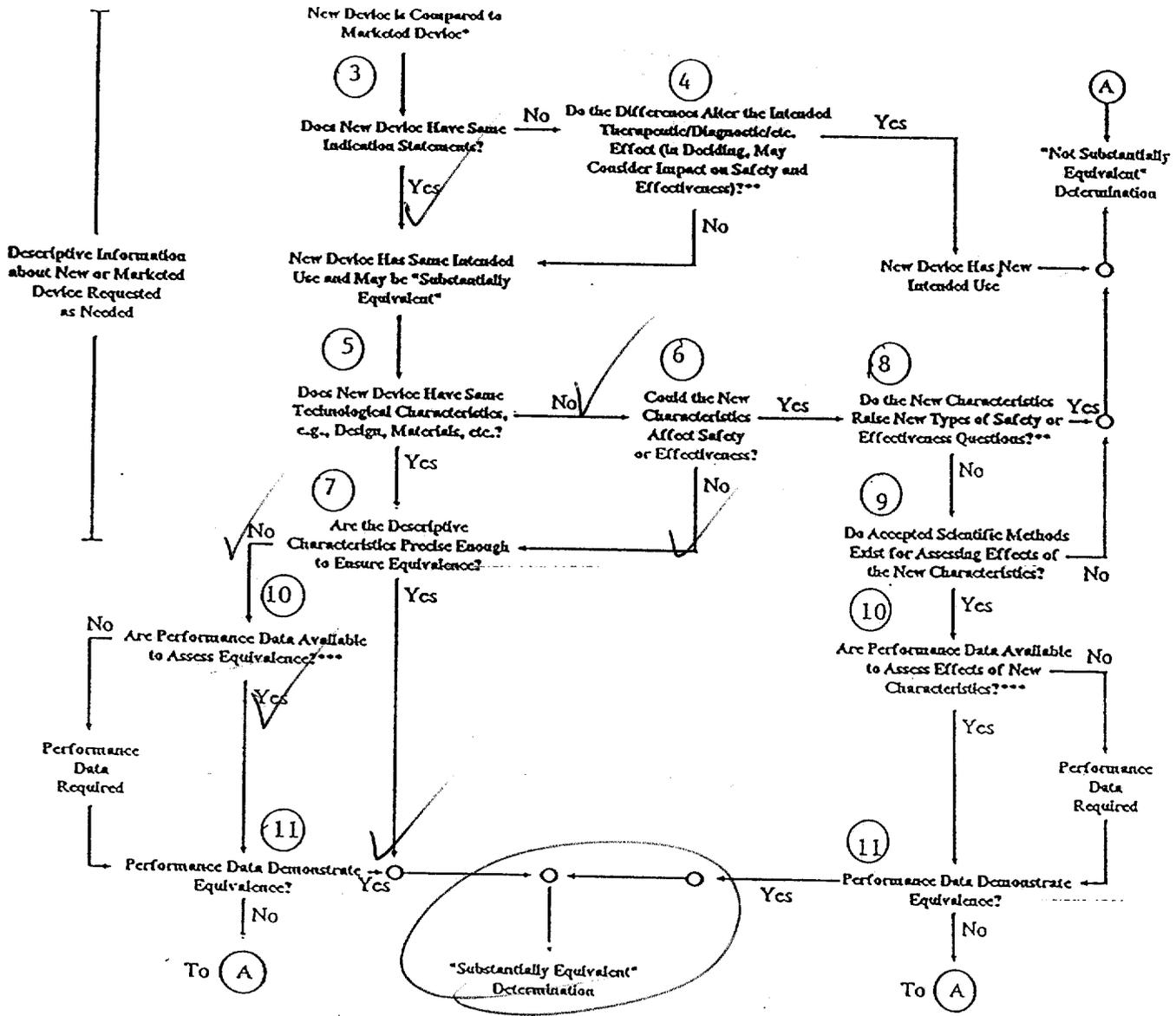
Predicate Product Code with class and tier: Additional Product Code(s) with panel (optional):

80/FMQ/I/880.6760

Review: Rutana Cuervo ON/DA 11-13-97
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 11/13/97
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- * 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

MEMO TO THE RECORD

510 (K) REVIEW

K972446

DATE: November 13, 1997
FROM: Irene Naveau

OFFICE: HFZ-480
DIVISION: DDIG/GHDB

COMPANY NAME: Cavity Free Kids, Incorporated
DEVICE NAME: Pedo Cush Pedo Cuddle

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

The Pedo Cush Pedo Cuddle is both a protective restraint and cushion for the purpose of securing a pediatric patient in a dental chair. It consists of a main body portion which has a number of attached flaps with hook and loop fasteners to fasten around the patient in order to hold the body in position during a dental procedure. The foam cushion, covered with a pillowcase, has an indentation at the top and at the buttock area to support the patient's head and buttocks in position. The Pedo Cush Pedo Cuddle has adhesive material on the underside as well as straps which are used to tie around the dental chair, this stabilizing the device.

The Pedo Cush Pedo Cuddle is available in four sizes: extra small, small, medium, and large and are designated for particular ages, however, the child's height and weight should be considered when selecting the appropriate size.

The restraint is composed of cotton or a combination of cotton and another fabric; the foam cushion is encased in a vinyl cover covered with a cotton jacket.

2. INTENDED USE: To protect both patient and clinician from sudden and unsafe patient movement

3. DEVICE DESCRIPTION:

- A. Life-supporting or life-sustaining: No
- B. Implant (short-term or long-term): No
- C. Is the device sterile? No
- D. Is the device for single use? Yes, for single patient use. It is recommended that the Pedo Cush Pedo Cuddle be laundered following use in preparation for use with another pediatric patient.
- E. Is the device for prescription use? Yes
If yes, is prescription labeling included? Yes
- F. Is the device for home use or portable? The device is portable and for use in the dental office only.
- G. Does the device contain drug or biological product as a component? No

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Page 2 of 510(k) review

- H. Is this device a kit? No
- I. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): N/A
- J. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status: Papoose Board, Olympic Medical Company, Preamendment
- K. Submission provides comparative specifications
 - a Yes
 - comparative in vitro data b No
 - performance data c Yes
 - animal testing d No
 - clinical testing e Yes
 - biocompatibility testing f No
- L. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

The Pedo Cush Pedo Cuddle is similar to the Papoose Board in intended use, and performance, and laundering. This device, however, has the foam cushion that provides more comfort for the patient's head and torso while the Papoose Board consists of a vinyl covered board with a plastic head stabilizer which would seem to be less comfortable.

The sponsor states that this device was tested on patients with behavior ranging from uncooperative and fearful patients to hysterically out of control patients, and that the patients were successfully managed during dental procedures. In 1982 and for twelve years thereafter, the sponsor used the predicate device (Papoose Board) for securing uncooperative patients. The Papoose Board was replaced with the Pedo Cush Pedo Cuddle (b)(4) years ago, and was used on over a thousand patients by (b)(4) (b)(4). Refer to Exhibit VII for a summary of the performance of this device with (b) patients (b)(4)(b) (b)(4) received dental treatment using this device in the month of August, 1997. Exhibit VII also includes the results of the use of this device with (b) patients and includes (b)(4)

The labeling includes a prescription statement, materials, size, and laundry instructions, as well as position labeling. The user will also receive an insert related to instruction and warning for the use of the Pedo Cush Pedo Cuddle restraint. It lists directions in placing the device on the dental chair and the method of placing the child in the restraint. Warnings include statements, e.g., the device is not to be used as punishment, the child should not be left alone while in the restraint, and that thin clothes are recommended to prevent hyperthermia.

Based on the information provided in this premarket notification, I believe that this device is as safe and effective as the Papoose Board, and that no new issues of safety and effectiveness exist. I believe that this device is substantially equivalent to the Papoose Board, a preamendment device, manufactured by Olympia Medical Company.

- M. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? Yes

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Page 3 of 510(k) review

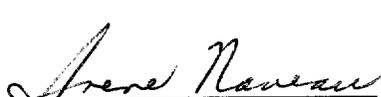
N. RECOMMENDATION:

I believe that this device is equivalent to: 80 FMQ

Classification should be based on: Protective Restraint

880.6760

Class: I

 11/13/97
Irene Naveau
Irene Naveau

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K972446

Reviewer: Irene Naveau

Division/Branch: DDIGD/GHDB

Device Name: Pedo Cush Pedo Cuddle

Product To Which Compared (510(K) Number If Known): Papoose Board, Olympia Medical Company, Preamendment

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?		X	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		X	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	X		If NO = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: To protect both patient and clinician from sudden and unsafe patient movement.
2. Device Description: See SE memo dated November 13, 1997.

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EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

5. Describe the new technological characteristics: The base of the Pedo Cush Pedo Cuddle is constructed, not of rigid wood, but with a foam cushion that allows for greater comfort for the pediatric patient. It is also constructed in a way that allows it to be fastened to the dental chair for added protection for an unmanageable child
6. Explain how new characteristics could or could not affect safety or effectiveness: The Pedo Cush Pedo Cuddle does not affect safety or effectiveness. Studies performed by the sponsor demonstrate that the device is safe and effective. See Section VII submitted October 9, 1997.
7. Explain how descriptive characteristics are not precise enough: Additional information was required to include related to labeling, and performance data.
10. Explain what performance data is needed: This device was tested on over 1000 pediatric patients requiring dental care. A summary of this data and a sampling of the testing was required. This data was submitted by the sponsor.
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
The performance data demonstrated that the Pedo Cush Pedo Cuddle was safe and effective for pediatric patients. It is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 15, 1997

CAVITY FREE KIDS, INC.
1224 ARCADE ST.
ST. PAUL, MN 55106
ATTN: VACHAREE S. PETERSON

510(k) Number: K972446
Product: PEDO CUSH PEDO
CUDDLE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K972446/SI



Dedicated to Healthy Teeth and Bright Smiles!

October 9, 1997

Ms. Irene Naveau/Ms. Marjorie Shulman
FDA Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

RECEIVED
OCT 14 1 36 PM '97
FDA/CDRH/ODE/DMC

Dear Ms. Naveau/Ms. Shulman:

The following document is in response to your request regarding clarity and additional information on our application for a 510(k). Our Number is K972446. I have included a copy of the letter received September 19, 1997 from the desk of Marjorie Shulman, plus two pages copied from the original submission that include our document number, etc.

Thank you for your guidance and expertise given to expediting the approval of this product application. If you have any additional questions please give me a call at 612-774-0583.

Sincerely,

Vacharee S. Peterson

/das

SK-56

REC'D 4/19/99

Records processed under FOIA Request # 2016-1365; Released by CDRH on 05-16-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

September 08, 1997

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

CAVITY FREE KIDS, INC.
1224 ARCADE ST.
ST. PAUL, MN 55106
ATTN: VACHAREE S. PETERSON

510(k) Number: K972446
Product: PEDO CUSH PEDO
CUDDLE

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

8/29

Marjorie Shulman

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

JB

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0059.
Expiration Date: March 31, 1996.

DEVICE LISTING

Complete and Return to:
**Food and Drug Administration
Center for Devices and Radiological Health
Office Automation and Information Processing Branch (HFZ-300)
2098 Gaither Road
Rockville, MD 20850**

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(g)(2) and may be a violation of 18 U.S.C. 1001.

1. DOCUMENT NUMBER A897491	2. BAR CODE	3. REASON FOR SUBMISSION <input checked="" type="checkbox"/> New Listing <input type="checkbox"/> Update to Device Already Listed <input type="checkbox"/> Delete Listing	4. REPORT DATE		
			MO.	DAY	YR.
			05	16	97

5. OWNER / OPERATOR NAME OR U.S. DESIGNATED AGENT NAME Cavity Free Kids Company	6. OWNER / OPERATOR ID NUMBER
---	-------------------------------

7. ADDRESS (Check if same as submitted on FDA Form 2891)
a. STREET **1224 Arcade Street**

b. CITY, STATE, ZIP CODE ST. Paul MN. 55106	c. FOREIGN COUNTRY
---	--------------------

8. CLASSIFICATION NAME Protective Restraint	9. CLASSIFICATION NUMBER 80 FMA
---	---

10. PROPRIETARY NAME (Brand Name)
Pedo Cush PedoCuddle or in short Pedo Cush

11. COMMON OR USUAL NAME
Protective Restraint

12. FOR U.S. DESIGNATED AGENTS OF FOREIGN ESTABLISHMENTS
a. ARE YOU LISTING FOR A FOREIGN OWNER / OPERATOR?
 YES (Indicate below the owner/operator ID number, firm name, address, and name of foreign country. Attach a letter of authorization.)
 NO

b. OWNER / OPERATOR ID NUMBER (If new listing, indicate, "none") NONE	c. FIRM NAME
---	--------------

d. ADDRESS	e. FOREIGN COUNTRY
------------	--------------------

13.	REGISTRATION NUMBER	14. ESTABLISHMENT NAME (Identification of Sites Where Listed Device is Produced)	15. ESTABLISHMENT TYPE												
			C	D	E	M	R	S	T	U	X				
A		Angel Industries Sewing													
B		(Domestic Establishment)													
C		Cavity Free Kids	✓	✓							✓				
D		Angel Industries Sewing	✓	✓			✓								

Reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Reports Clearance Officer, PHS, Hubert H. Humphrey Building, Room 721-B, 200 Independence Avenue, S.W., Washington, DC 20201, Attn: PRA and to: Office of Management and Budget, Paperwork Reduction Project (0910-0059), Washington, DC 20503

Please **DO NOT RETURN** this form to either of these addresses.

16. SIGNATURE **Vacharee Peterson DDS.**
Questions? Contact FDA/CDRH/OCE/DID at www.fda.gov or 301-796-8118

PUBLIC HEALTH SERVICE
 FOOD AND DRUG ADMINISTRATION

Form Approved; OMB No. 0910-0059.
 Expiration Date: March 31, 1996.

INITIAL REGISTRATION OF DEVICE ESTABLISHMENT

(Shaded Areas are for Information Use Only)

VALIDATION

FORN THIS FORM TO: Food and Drug Administration, Center for Devices and Radiological Health, Office Automation and Information Processing Branch (302), 2098 Gaither Road, Rockville, MD 20850

1. REGISTRATION NO.

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Reports Clearance Officer, PHS, Herbert H. Humphrey Building, Room 3534, 200 Independence Avenue, S.W., Washington, DC 20201 and to the Office of Management and Budget, Paperwork Reduction Project (0910-0059), Washington, DC 20503

Reports Clearance Officer, PHS
 Herbert H. Humphrey Building, Room 3534
 200 Independence Avenue, S.W.
 Washington, DC 20201
 Attn: PRA

Office of Management and Budget
 Paperwork Reduction Project (0910-0059)
 Washington, DC 20503

FORN this form to either of these addresses.

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)) of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.

SECTION A

2. ESTABLISHMENT NAME Cavity Free Kids Inc.		3. RECORD DATE (Mo.) (Day) (Yr.) 05 17 1997		
4. NUMBER AND STREET 1224 Arcade St.		5. CITY ST. Paul		6. STATE MN
7. ZIP CODE 55106		10. PREPRODUCTION REGISTRATION <input type="checkbox"/> YES <input type="checkbox"/> NO		
6. FOREIGN COUNTRY		9. ESTABLISHMENT TYPE (See Instruction Booklet) <input checked="" type="checkbox"/> C <input checked="" type="checkbox"/> D <input type="checkbox"/> E <input type="checkbox"/> M <input type="checkbox"/> R <input checked="" type="checkbox"/> S <input type="checkbox"/> T <input type="checkbox"/> U <input type="checkbox"/> X		

SECTION B

11. OWNER/OPERATOR Vacharee S. Peterson Cavity Free Kids Inc.		12. OWNER/OPERATOR I.D.		
13. NUMBER AND STREET 1224 Arcade St.		14. CITY ST. Paul		15. STATE MN
16. ZIP CODE 55106		18. TELEPHONE NUMBER—IF DIFFERENT FROM THAT OF OFFICIAL CORRESPONDENT (Area Code) (Number)		

SECTION C

19. OFFICIAL CORRESPONDENT Vacharee S. Peterson		20. TELEPHONE NUMBER (Area Code) (Number) (612) 774-0583		
21. BUSINESS NAME Cavity Free Kids Inc.				
22. NUMBER AND STREET 1224 Arcade St.		23. CITY ST. Paul		24. STATE MN
25. ZIP CODE 55106		27. FAX NUMBER (Area Code) (Number) (612) 774-1997		

SECTION D

28. OTHER BUSINESS TRADING NAMES
 (Enter any other name which the establishment in field #2 uses. Do not list Registered trademarks or names of private label distributors. This is usually any name such as a brand name which is not the firm name).

SEQ	ESTABLISHMENT NAME	SEQ	ESTABLISHMENT NAME
S01	NONE	S03	
		S04	

29. CERTIFYING AGENT (Typed Name)

30. TITLE AND PHONE NUMBER (Area Code) (Number)

SECTION E

31. SIGNATURE OF OFFICIAL CORRESPONDENT 	32. TITLE Founder
---	-----------------------------

510 (K) Notification

Date: 5-16-97

Revised correspondence 9/30-97

Applicants name and address:

Cavity Free Kids
1224 Arcade St.
St. Paul, Minnesota
55106

Contact Person:

Dr. Vacharee Peterson
Or
Dr. Dale Saxon

Telephone Number:

612-774-0583

Fax Number:

612-793-0967

Purpose of Submission: Premarket notification to the FDA so that our company may sell to the Dental Health Professionals, the PedoCush/Pedo Cuddle, a dental physical security device for the young patients who are not able to cooperate and for the mentally incompetent patients.

Trade Name:

Pedo Cush Pedo Cuddle

Common Name:

Protective restraint

Classification name:

Protective restraint

Establishment registration

Number:

Pending (per FDA letter dated 6/17/97)

Procode(s):

80FMQ

Address of manufacturing Site:

Angel Industries, Inc.
488 South Robert St.,
St. Paul, Minnesota 55107
612-224-7591

Signature of the Applicant:

A handwritten signature in black ink, appearing to be "Dale Saxon", is written over a horizontal line. The signature is stylized and cursive.A small, stylized handwritten mark or signature in the bottom right corner of the page.

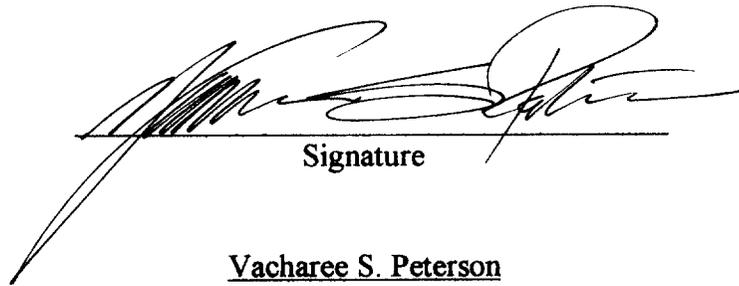
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Premarket Notification: Truthful and accurate statement
[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as the President/Owner of Cavity Free Kids, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Signature

Vacharee S. Peterson
Typed name

10-6-97

Date

K972446

[Premarket notification [510 (k)] Number]

For a new submission, leave the 510 (k) number blank. Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510 (k) submitter]



Device Name:

Trade Name: Pedo Cush Pedo Cuddle

Common Name: Protective Restraint

Classification name: Protective Restraint (per 21 CFR 880.6760)

Registration Number:

K 972446

Classification:

Class I

Panel: General hospital and Personal use Devices

Product Code: 80FMQ

Labeling:

The box containing Pedo Cush Pedo Cuddle is made of paper carton approximately 6 inches x 21 inches x 21 inches. A bold print on the front of the package says:

Pedo Cush Pedo Cuddle

Protective restraints device for use in dental office

Federal law restricts this device to sale by or on the order of a dentist

To insure proper usage, please read the manual carefully for instructions before using this product.

Questions, comments, or suggestions please call 612-774-0583 or write to:

Cavity Free Kids, 1224 Arcade St., St. Paul, MN. 55106

The appropriate size will be checked (x) on the box.

Extra small (6 months to 2 years old)

Small (2 years to 4 years old)

Medium (4 years to 6 years old)

Large (6 years to 8 years old)

*Size fitting may vary in accordance with child's height and weight



Device Labels:

The manufacturer, product identification and the cleaning instructions are on the same tag as shown on the attached sample.

- **Exhibit I:** See appendix (p.12)

Label A: size label. The abbreviation for the various sizes will be displayed next to the device label: XS (extra small), S (small), M (medium), L (large)

Label B: materials label. Material and Laundry

Label C: position label. The instructions will be displayed in the following manner:
Front Side: Facing the child

- **Exhibit IIA:** See appendix (p.13,14)

Instructions for Pedo Cush Pedo Cuddle use. The specific warnings, illustrations of hazards, cautionary information, application steps and instructions for use are explained in the instructions.

- **Exhibit IIB:** See appendix (p.15)

Illustrations and dimensions corresponding to the age of the child are included in the Exhibit

- **Exhibit III:** See appendix (p.16)

Sample of the Informed Consent Form which must be signed.

Device Description:

A combination pediatric restraint and cushion for a dental patient. The restraint is made of cloth (cotton or the combination of cotton and other fabric) and has single or multiple flaps with hook and loop fasteners. The cushion (foam) insert is encased in a hospital ticking (vinyl) cover [3M product], sheltered by the cloth (cotton) jacket. An optional adjustable web belt is supplied to secure the cushion to the dental chair. There is a tag at the top identifying the head.

- **Exhibit IV:** See appendix (p.17-20)

Pictures of the Pedo Cush Pedo Cuddle in position

Statement of 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.

Physical specifications:

Pedo Cush Pedo Cuddle comes in four sizes; extra small, small, medium and large. Please refer to Exhibit II in the appendix for specific size and age correlation. The Pedo Cuddle and the cover (jacket) of the Pedo Cush is made out of cotton, the insert is made out of foam covered by a waterproof vinyl. Note that in some situations this product may be made to certain specifications to fit a specific dental chair. If requested, the headrest cover may be added to attain a customized fit and stability. If desired, the cotton fabric ties may be fabricated with a buckle lock system to fit a certain dental chair.

Mechanical Specifications:

The Dental Chair Stabilizer portion of the Pedo Cuddle has the Dental Chair Attachment which may be in the form of ties for attaching the unit to the dental chair or the buckle system (if the customer who is a dentist wishes to have a custom fit for his specific dental chair). Once the ties or buckles affix the Pedo Cuddle portion to the chair the Pedo Cuddle and Chair act as one.

The Arm Chest Flap portion of the Pedo Cuddle is sewn onto the Dental Chair Stabilizer portion. It is used to wrap the uncooperative child so that... a) the child's arms will not grab the operating equipment, pull the dentists hair or punch the assistant, b) the child will not throw himself out of the dental chair. At times it is necessary to ask the parent(s) and/or staff to help gently but firmly hold the child's body for additional stability.

Stabilizing the child's head can be obtained by tucking his/her head between the dentist's chest and the arm or one of the staff can hold the child's head gently but firmly, simultaneously massaging the child's forehead inducing a soothing effect.

The Pedo Cush portion of the Pedo Cush Pedo Cuddle protects the child in two ways... a) it supports the child's knees, preventing the knees from being pushed against the dental chair in a harsh or painful fashion [See Exhibit IV... picture 1] b) it prevents the child from kicking the equipment, parent or the assistant. The Pedo Cush is unique in that it has the capability of functioning as a converted Adult dental chair by supporting the child's buttocks, preventing him from sliding downward, and allowing effective and comfortable dentistry to take place.

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)

Prescription Use _____

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



The material strength and reuse durability:

Since the Pedo Cush Pedo Cuddle is made out of cotton, it has the wear and durability similar to other cotton clothing ... that is it can be used several times before showing fading and any fraying. After testing this product for three years in our clinic we found that it lasted about 50 to 100 usage's or about six months to one year depending upon how often it is used. It should be noted that we recommended the jacket to be washed after each use. Moreover, if the children who have used the Pedo Cush Pedo Cuddle are very strong in their uncooperative behavior then the wear and tear is more evident and reduces the life of the product.

Biological Specifications:

Since only the cotton will be in contact with the child's clothes and skin it makes Pedo Cush Pedo Cuddle highly biocompatible with the human skin.

Descriptive comparison to legally marketed device:

The legally marketed device to which substantial equivalence is claimed is the Olympic Papoose Board manufactured by Olympic Medical, Seattle, WA. This is a Class I device which has been granted marketing clearance by FDA following submission of a 510(k).

Table I	Pedo Cush Pedo Cuddle	Papoose Board
Intended use	To protect the child from injuring himself/herself during dental treatment as a result of out of control behavior	To restrain the uncooperative child for necessary treatment.
Target Population	Children or mentally ill patients; to be used by dentists, or under dentists direction	Children or mentally ill patients, primarily for use by medical doctors, can be used by dentist
Labeling	Includes instructions for use and cautions	Same
Design specifications	Wrap and cushion, each having flaps with Velcro closures. Wrap secures torso, cushion secures buttocks and legs	Wrap with armholes and Velcro closures, stiff board as back rest

	Pedo Cush Pedo Cuddle (cont.)	Papoose Board (cont.)
Materials	Wrap (including flaps, straps, and headpiece) made of soft cotton cloth backing, has Velcro closures. Foam cushion enclosed in soft cotton pillowcase having soft cotton flaps with Velcro closures	Flaps and straps made of cotton, Velcro closures
Performance data	Controls side-to-side and up-and-down motion of patient in dental chair. Tested on over one thousand child patients with behavior ranging from uncooperative and fearful to hysterically out of control. Successfully calmed patients to allow dental procedures to be performed	Controls side-to-side and up-and down motion of patient in dental chair. Currently on the market.
Sterility	Can be laundered and bleached	Flaps and straps can be laundered and bleached, board cannot
Safety	Secures patient firmly and comfortably in dental chair	Cannot be secured to dental chair; child can slide downward in chair if he/she kick in an attempt to escape
Anatomical sites	Secures patient's torso and legs	Same
Human factors	Comfortable and relaxing for patient	Less comfortable due to stiffness of board
Compatibility with other devices	Can be used with any standard dental chair	Same
Where used	Dental office	Dental or medical office, emergency room

How differences may effect safety and effectiveness:

Pedo Cush Pedo Cuddle is safer and more effective because the presence of the cushion and the fact that the restraint can be secured to the dental chair prevents the patient from sliding out of the chair; the softness of the material provides greater comfort and is therefore more relaxing for the patient.

Pedo Cush Pedo Cuddle is covered by U. S. patent # 5,425, 381 and is described in more detail therein. A copy of this patent is included in the Appendix (p.21-26). The information on the Papoose Board is included as Exhibit VIA. For proof of the Papoose Board being marketed before May 1976 see Exhibit VIB.

Performance Data supporting equivalence:

Bench and simulated use tests: our clinic has served our community since the summer of 1982. For the first twelve years we have used the Olympic Papoose Board system for physical security during uncooperative behavior. Although we found it useful it was our experience that a child could easily slide down in the dental chair or struggle so hard that they literally threw themselves from the chair. Growing out of this challenge we developed our own physical security device that is similar to the Papoose Board wrapping component. We then continued to add features that would help secure the child in a more confident and comfortable fashion. Our device came to be called the Pedo Cush Pedo Cuddle or in short *PedoCush*. For the (b)(4) (b) years we have replaced the Papoose Board, utilizing the Pedo Cush Pedo Cuddle in our clinic. We have found it to be the superior product in protecting the child in dental treatment. For the sake of simplicity in reporting to the FDA the effectiveness of its use I chose the month of August, 1997 to serve as a sampling of the behavior management done in our clinic. See Appendix (p.43-49) Exhibit VII.

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	Mesh fabric wrap with Velcro closures. Vinyl-covered board, plastic head stabilizer.

<p>Performance</p>	<p>vinyl inserted in cotton outer jacket</p> <p>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; successsfully managed the patients to allow dental procedures to be performed.</p>	<p>Controls side-to-side and up-and-down motion of patient in dental chair. Currently on market.</p>
<p>Sterility:</p>	<p>Jacket can be laundered and bleached.</p>	<p>Same</p>
<p>Safety:</p>	<p>Secures patient firmly and comfortable in dental chair.</p>	<p>Same</p>
<p>Anatomical sites:</p>	<p>Secures patient's torso and legs</p>	<p>Same</p>
<p>Human factors:</p>	<p>Comfortable and relaxing for patient</p>	<p>Same</p>
<p>Compatibility with other devices:</p>	<p>Can be used with any standard dental chair</p>	<p>Same</p>
<p>Where used:</p>	<p>Dental office</p>	<p>Same</p>

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 patient's 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:

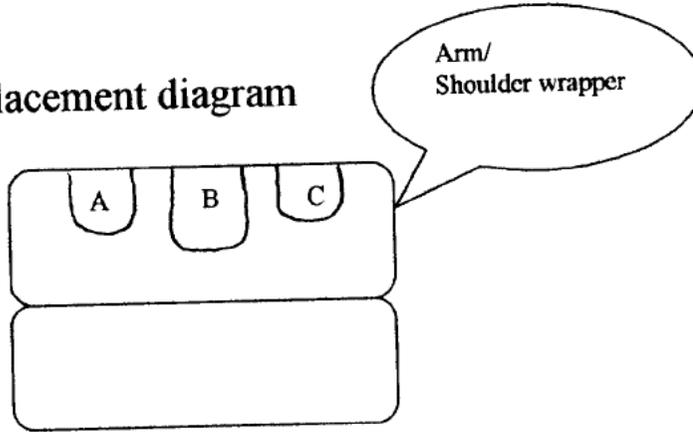
To protect both patient and clinician from sudden and unsafe patient movement.

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

Exhibit I

Label placement diagram



Label A

ES

S

M

L

Label B

Cover:

100% Cotton
Velcro fasteners

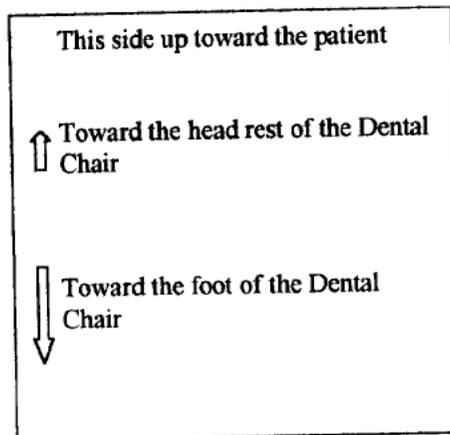
Cushion:

Inner: Foam
Middle: Water Proof Hospital Ticking
Outer: 100 % Cotton... Velcro Fasteners

Laundry: Remove the waterproof hospital ticking (including the foam), then machine wash warm. Bleach as necessary. Tumble dry low. **b**

U. S. Patent #5,425,381
Cavity Free Kids
1224 Arcade St.
St. Paul, MN. 55106 USA
Tel: (612) 774-0583

Label C



Instructions and Warning for PedoCush

Congratulations! You have purchased a fine product designed with the personal security of children in mind. We want to ensure your every success in using the *PedoCush*. Please follow the directions included (study Exhibit IIB to choose appropriate sizing for patients age) for the best results.

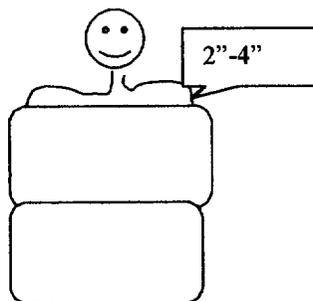
Prior to placing the child in the chair for treatment:

- Obtain informed consent from parent or person accompanying the child for treatment. (If you do not have an informed consent form contact Cavity Free Kids for a sample) [Exhibit III]
- Place the *PedoCush* jacket on the dental chair in the following manner. Slide the head flap over the headrest of the dental chair and fasten the strings to the arms of the dental chair. [Exhibit IV]

Place child in the dental chair and position in the best manner for you to do dentistry.

- Slide the *PedoCush* cushion up under the child's legs with the concave portion around the child's buttocks.

If you need to physically secure the child during treatment you may do so by simply pulling up the Velcro flaps to wrap the child. The 1st set should be approximately 2-4 inches from the top of the shoulder. The second set should be utilized as a wrap depending upon the anxiousness of the child. The leg flaps that are cushioned should encompass the knees and protect the shins.



It is important to note that as the patients behavior changes the amount of securing you need to do will also change. The *PedoCush* should **not** be used as a form of punishment. ***Its purpose*** is to protect the child from grabbing instruments or injuring himself/herself as a result of out of control behavior. **Never** leave a child unattended in the *PedoCush* or at anytime during dental treatment.

We strongly encourage the participation of a parent in treating the child. Invite the parents to stay in the room to help you secure the child's hands and feet. A gentle hand massage and the soothing words of a parent can often offer reassurance to the child and in fact make your job easier. If you would like further assistance please send for the instructional videotape. If you have comments or concerns please contact us at Cavity Free Kids 612-774-0583. We thank you for your patronage and wish you every success.

Laundering Instructions

The *PedoCush* jacket may be washed and bleached as often as needed by following these directions (also see care directions tag on device)

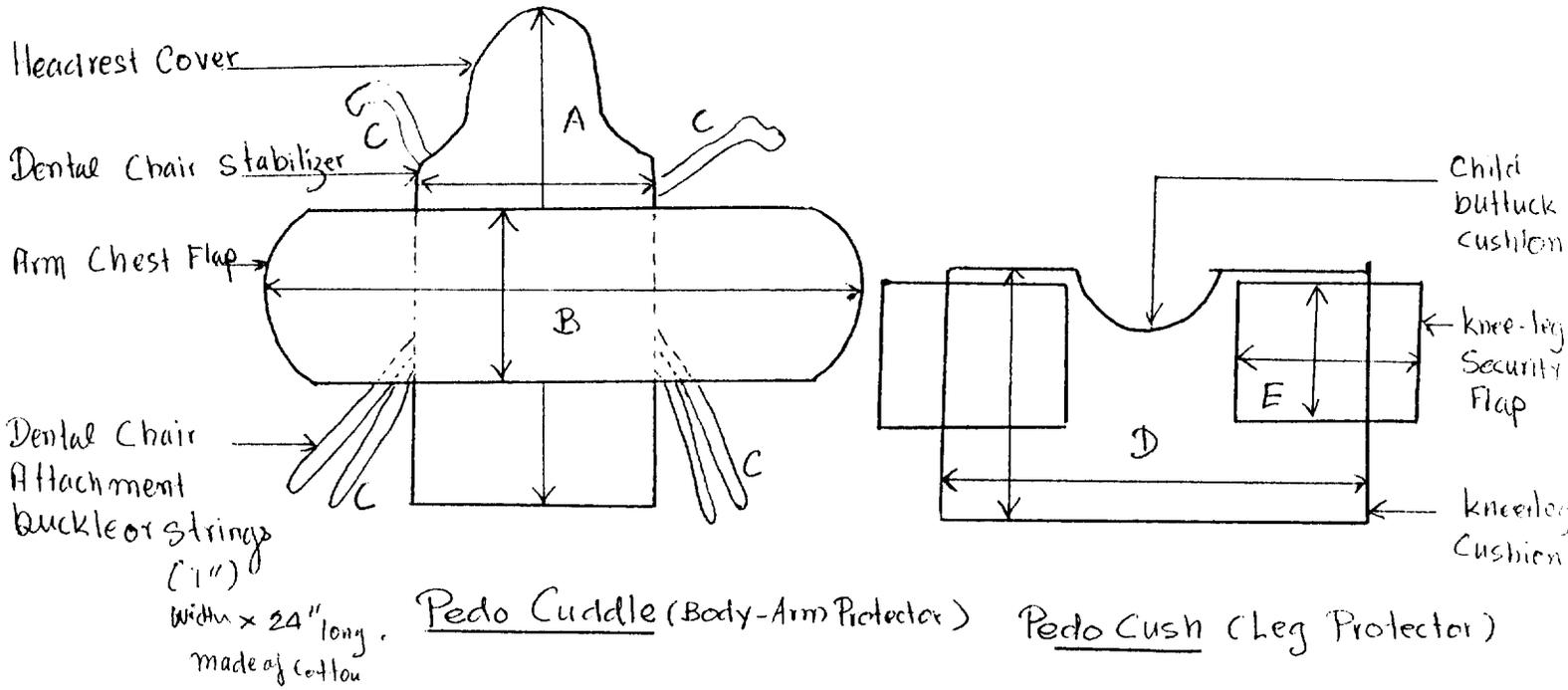
- Remove the cushion from the *PedoCush* by unzipping the jacket and removing the insert.
- Machine wash jacket with warm water; bleach as necessary. Tumble dry.
- If you have the model where the insert has the foam covered, wipe insert with hot, soapy water. Wipe dry.
- Reinsert cushion; zip jacket closed

Warning alert:

- This device is not to be used as a punishment device
- Thin clothes are highly recommended for the patient to prevent any threat of hyperthermia
- Never leave the child unattended while being wrapped with the *Pedo Cush* *Pedo Cuddle* (In fact, when in dental treatment never leave the child alone.)

Pedo Cush Pedo Cuddle

Dental Child Security Device Dimensions and Components



Pedo Cuddle (Body-Arm Protector)

Leg Protector

Size	Binding Color Code	Part A		Part B	
		Height	Width	Height	Width
XS	White	29"	15"	12"	29"
S	Red	30"	15"	15"	34"
M	Green	30"	15"	16"	39"
L	Blue	30"	15"	18"	46"

One Size

Part D	Part E
Height 18"	11"
Width 19½"	11¼"
<u>Part C</u> 1" x 24"	

Size/Age Recommendations for Pedo Cush Pedo Cuddle

Size	Ordering Code Number	Approximate Age
Extra Small	PC - XS	6 months - 2 year
Small	PC - S	2 year - 4 year
Medium	PC - M	4 year - 6 year
Large	PC - L	6 year - 8 year

BEHAVIOR MANAGEMENT INFORMED CONSENT

To the parent or guardian of:

Child's Name

Birthdate

As a concerned dentist, I would like to discuss with you the methods of managing your child's behavior during treatment. While children are usually cooperative and brave, sometimes they can become frightened by the equipment and the unknown experience. This is especially true for children younger than three years, but it also holds true for some older children as well.

In order to treat your child safely, we may have to use these aids:

- **Mouth Rester**—helps hold the child's mouth open in order for the dentist to have better access and prevents the child from biting down on a working drill. If a child falls asleep during the procedure, the Mouth Rester will enable the dentist to continue to work without waking the child up.
- **PedoCush / PedoCuddle**—secures and protects the child's body. A strong Velcro wrap and cushion help position the child on the dental chair. The child's arms, legs, and bottom are secured so that he/she cannot be injured by grabbing or kicking the equipment, the assistant, the parents, or the doctor.
- **Holding Assistant**—also helps secure the child to protect and position him/her on the dental chair. In addition, the holding assistant can comfort, massage, and soothe the child. Sometimes this person may be you, Mom or Dad.
- **Hand-Over-Mouth Exercise**—helps an out-of-control child overcome his/her screaming and listen to the dentist. Communication is always our goal. If a child can no longer hear because his/her own screaming is so loud, the dentist gently places a hand over the child's mouth and tells the child it will be removed when the screaming stops. The child's nose is never covered so he/she can always breathe. This exercise is not used with children under three who are not yet developmentally ready to cooperate with the dentist.

Note: Before giving us permission to use these aids, please read the back of this form to learn about other options for child behavior management. Also, do you have any questions? Please ask us before signing this consent.

- Yes, I give permission for my child to be treated at Peterson Dental Clinic. If necessary, you may use the Mouth Rester, PedoCush /PedoCuddle, Holding Assistant, and HOM exercise.
- No, I will not allow my child to be treated at Peterson Dental Clinic and will take him/her to another clinic for treatment. If I fail to do so, I know that my child's dental cavities may get worse.

Parent or Guardian

Date

ior

Date

Interpreter or Witness

Date

Behavioral Management Alternatives

At (b)(4) we take a non-drug approach to child behavior management, employing protective restraints when necessary. However, other clinic offer alternatives. Here is an overview of your options.

DO NOTHING AT THIS TIME

—PRO—

- We may be able to bring the child back at a later date when the child is more cooperative.
- We don't have to deal with the problem now.

—CON—

- The cavities will grow larger and eventually cause tooth pain.
- At that time, a more involved procedure will be more traumatic for the child.
- The cost of the procedure will be greater when the decay is more advanced.

GENERAL ANESTHESIA

—PRO—

- The child cannot offer resistance to treatment and the dentist can focus all attention of the procedure without being distracted by behavioral problems.

—CON—

- The child may need to remain in the hospital for observation overnight.
- There are some minor risks associated with drugs in terms of reaction and side effects—nausea, vomiting, and allergic reactions.
- Serious risks are involved with total loss of consciousness, including brain damage, stroke or heart attack, paralysis, or even death. Note that these occurrences, while legitimate risks, occur very rarely.
- A substantial cost is added to the procedure to cover the use of the hospital. This may be as high as \$1500 to \$2000.

SEDATIVE DRUGS

—PRO—

- The child is calmer and more manageable.
- Life is easier for the dentist during this procedure.
- Because their child is not in discomfort and crying, parents are not alarmed.

—CON—

- There are some minor risks associated with drugs in terms of reaction and side effects—nausea, vomiting, and allergic reactions.
- Sedative drugs do not always calm a truly out-of-control child and may make him/her more agitated.
- There is an additional cost to the procedure.

NON-DRUG APPROACH WITH PROTECTIVE RESTRAINTS

—PRO—

- There are no side effects or risks reported in the literature.
- The child is returned to the patent fully conscious.
- The protective wrap to secure the child is often needed only during the injection.

—CON—

- The child may be fearful, uncomfortable, and crying loudly.
- Parents may misunderstand the noise and commotion.

Exhibit IV

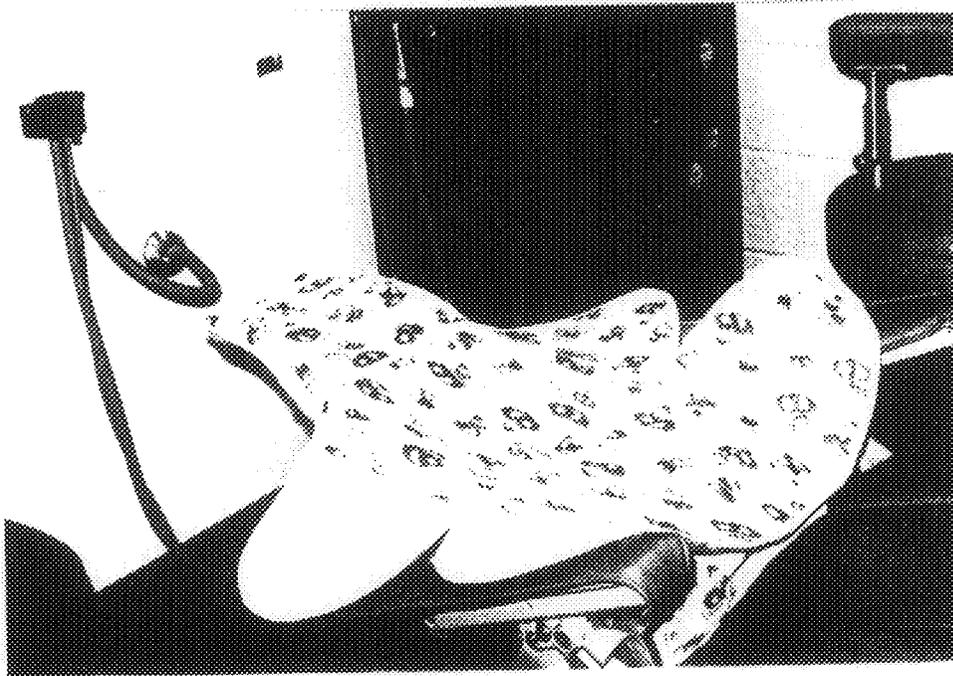


Photo #1: Recline the dental chair. Lay the Pedo Cuddle (front side up) on the adult dental chair, tying the top portion around the neck of the chair, tying the bottom strings around the arm braces of the adult chair (One set of strings around left arm rest brace, one set around right arm rest brace)



Photo #2: Position the Pedo Cushion on the seat of the adult dental chair as pictured.



Photo #3: Invite parent to place the child on the Pedo Cuddle, Pedo Cush.



Photo #4: The Doctor and assistant are now ready to wrap the child.

4

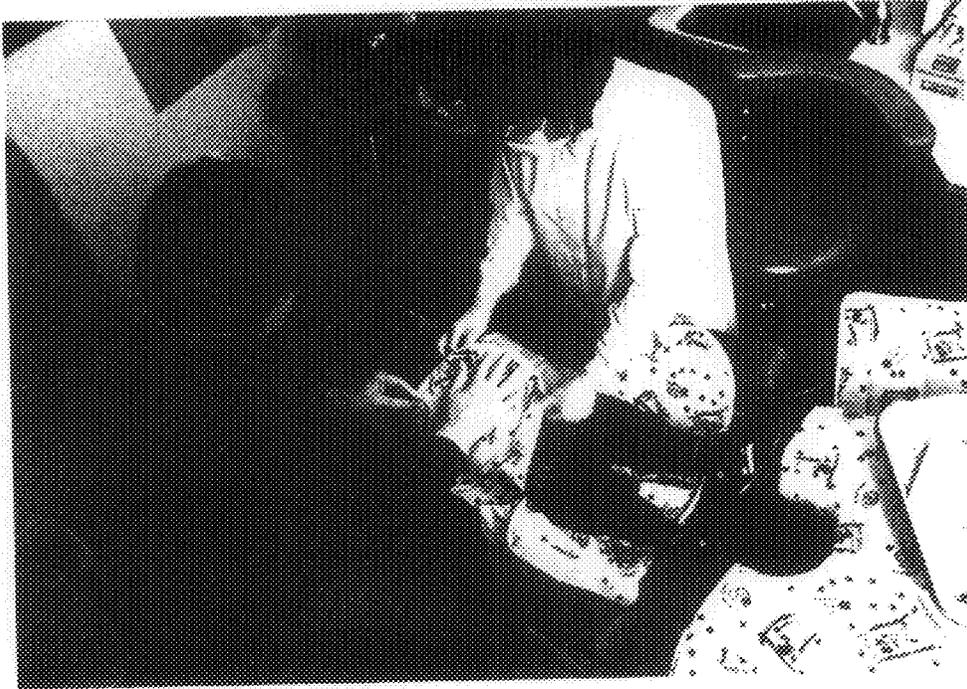


Photo #5: Secure the top set of wrappers. If the child raises his arms to fight treatment, the doctor can gently place the arms down while the assistant secures the wrap. (Notice that the shoulders are about 2"-4" above the border of the top wrapper.)

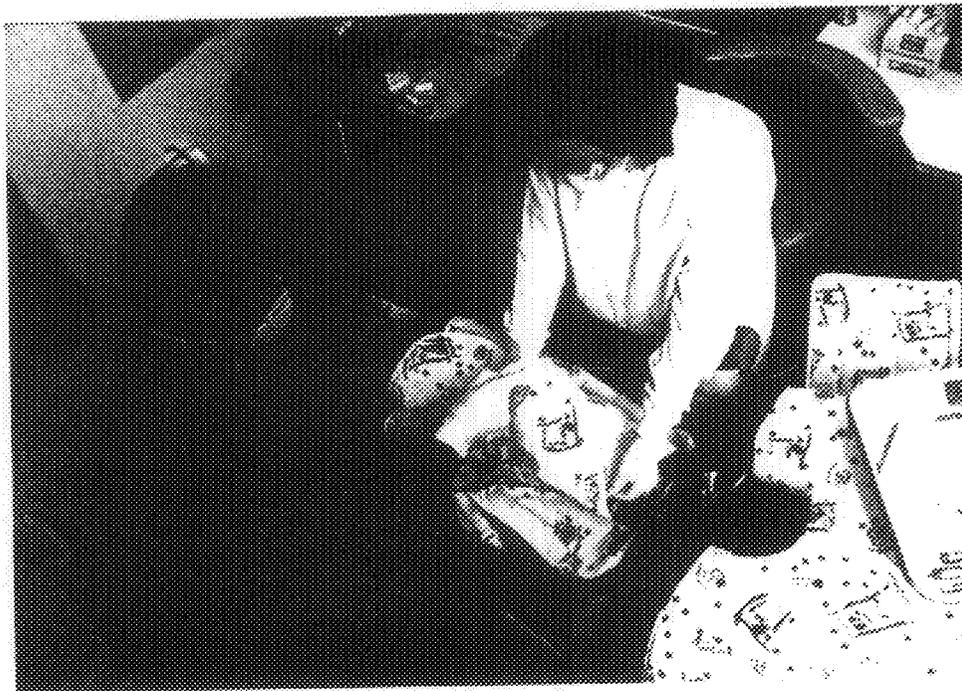


Photo #6: Secure the second set of wrappers to stabilize the mid section of the child.

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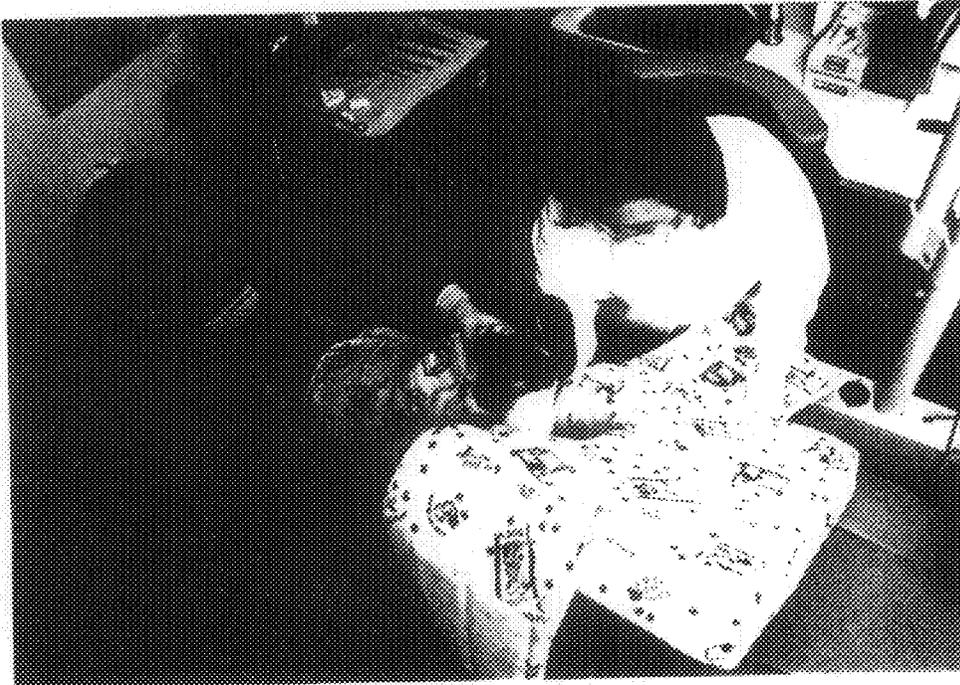


Photo #7: Position the Pedo Cushion to support the child's buttocks, thus converting the adult dental chair into a pedo chair.

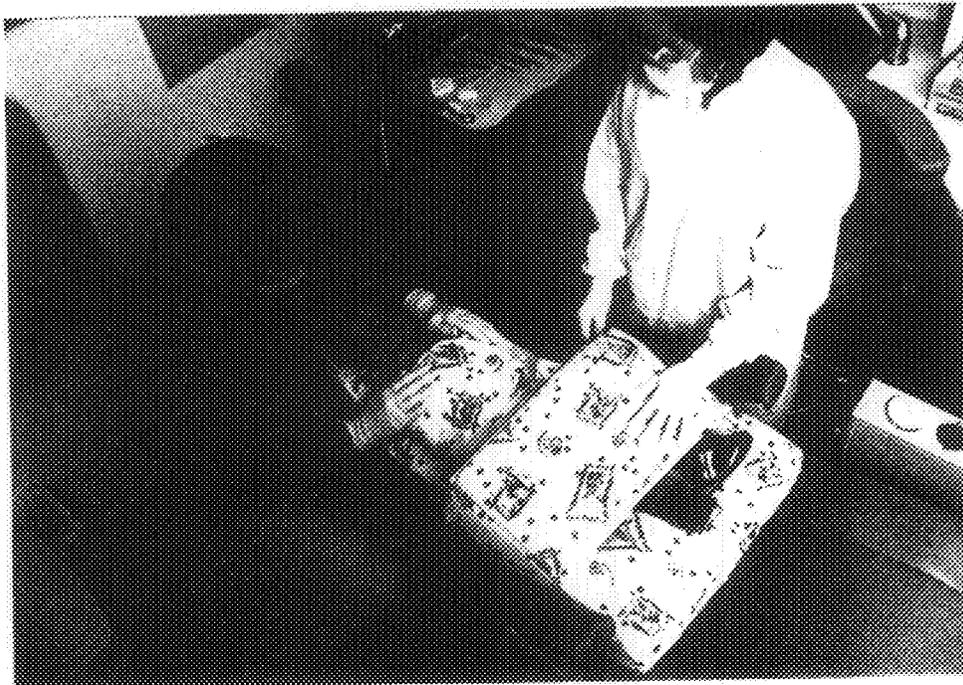


Photo #8: The child is secure and snug, ready to receive effective dental treatment.



US005425381A

United States Patent [19]

[11] Patent Number: 5,425,381

Peterson et al.

[45] Date of Patent: Jun. 20, 1995

[54] PEDIATRIC RESTRAINT AND CUSHION
[76] Inventors: Vacharee S. Peterson; Catherine T. Boler, both of 1224 Arcade St., St. Paul, Minn. 55106

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5,129,406 7/1992 Magnusen 128/873

[21] Appl. No.: 349,243

Primary Examiner—Michael A. Brown
Attorney, Agent, or Firm—Thomas B. Tate

[22] Filed: Dec. 5, 1994

[51] Int. Cl. A61B 19/00
[52] U.S. Cl. 128/869; 128/876
[58] Field of Search 128/845, 846, 869-876; 5/630, 632, 633, 636, 647, 648, 628, 655, 424

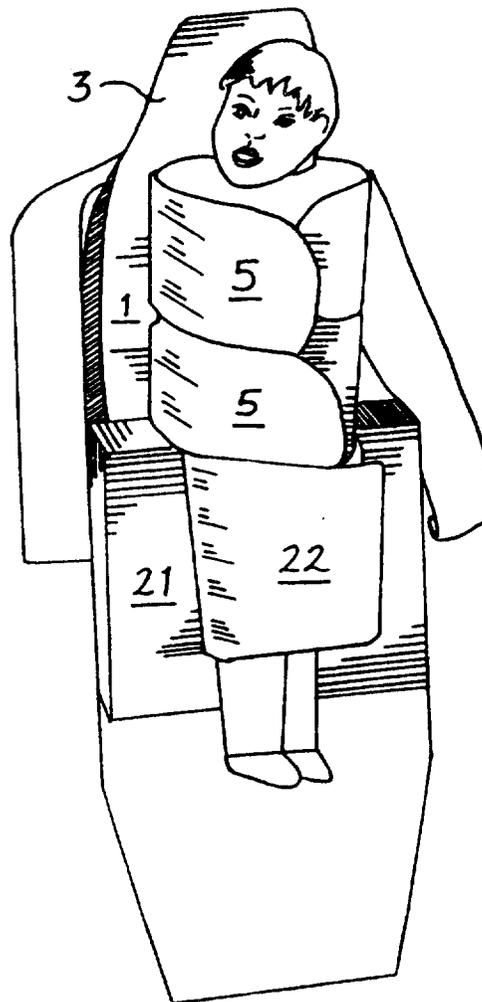
[57] ABSTRACT
A combination pediatric restraint and cushion for a dental patient. The restraint is made of cloth with an adhesive backing, and has a plurality of flaps with hook and loop fasteners, a plurality of straps, and a headpiece. The cushion is encased in a pillowcase which has an adhesive backing and has flaps with hook and loop fasteners, and has an arcuate indentation at its top end.

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1 Claim, 4 Drawing Sheets



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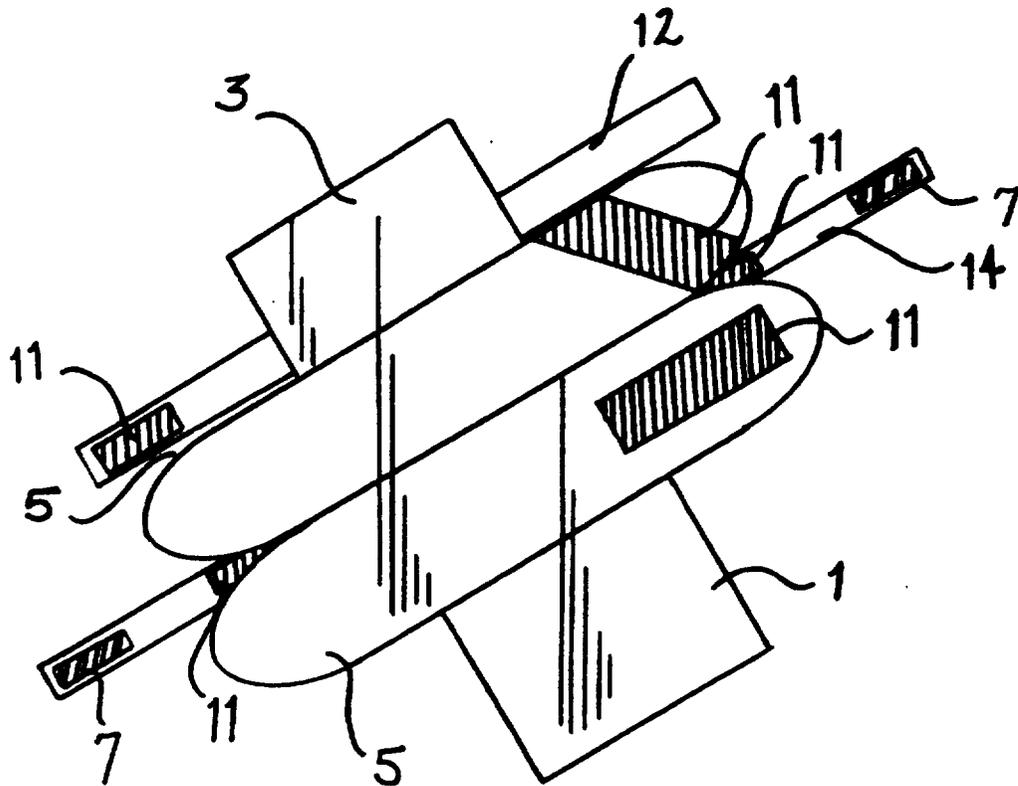


FIG. 1.

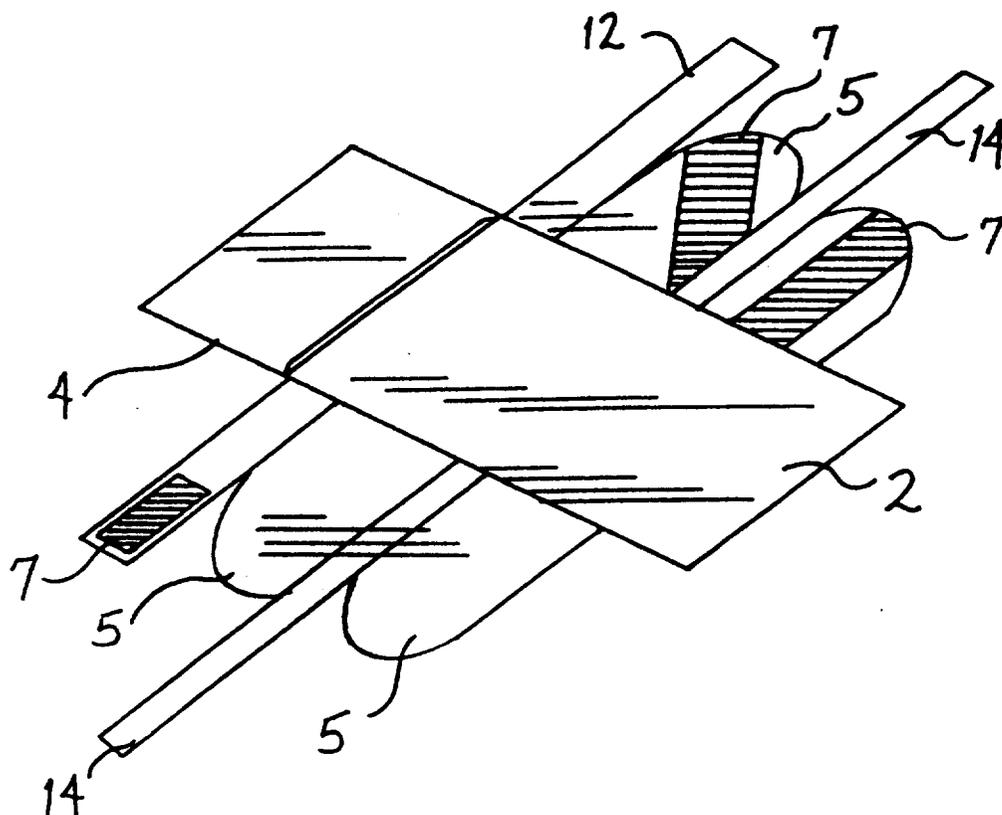


FIG. 2.

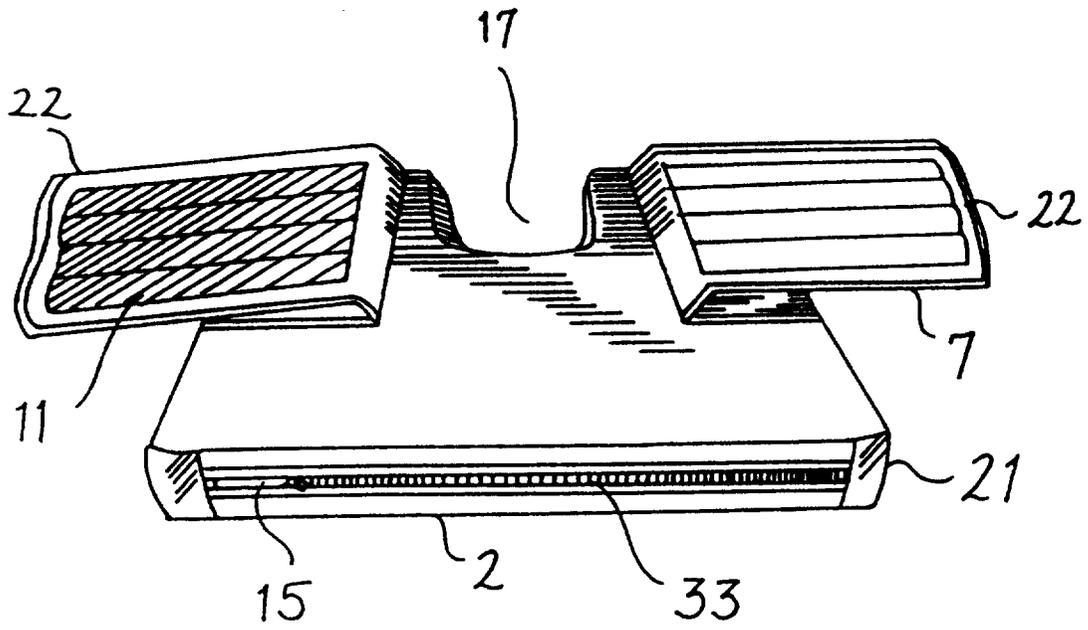


FIG. 3.

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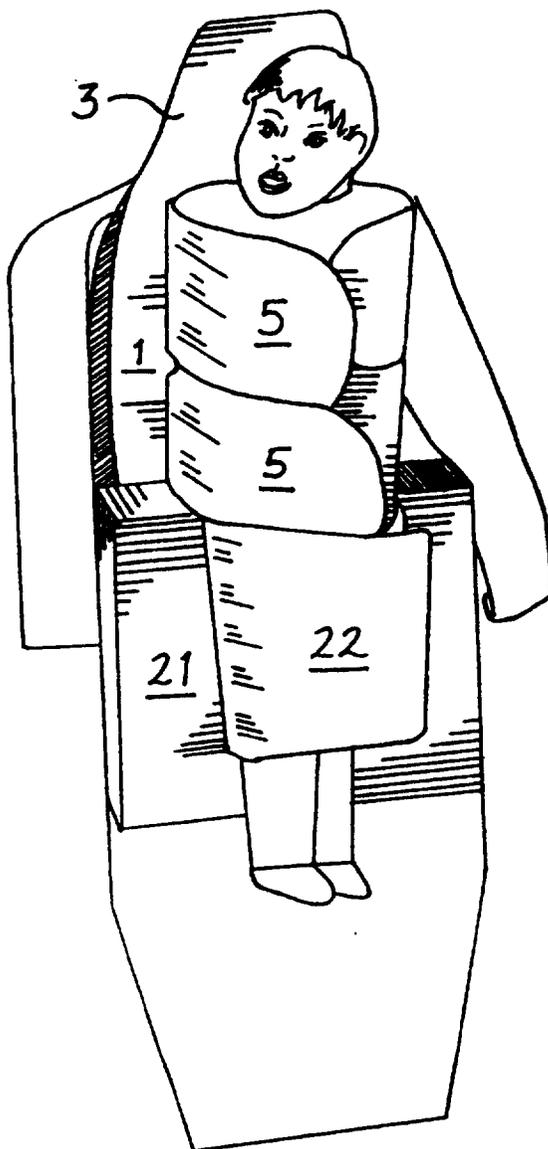


FIG. 4.

PEDIATRIC RESTRAINT AND CUSHION

SUMMARY AND BACKGROUND OF THE INVENTION

When a pediatric dental patient is restless and uncooperative, it is often necessary for the dentist to use a restraining device to hold the child in position in the dental chair long enough for the dentist to complete the necessary work. The two devices most commonly used for this purpose are the Olympic Papoose Board manufactured by Olympic Medical, which is a Velcro wrap which has armholes and a stiff board upon which the child's back rests, and the Pedo-Wrap manufactured by Clark Associates, which is a stiff pillow device with a mesh and Velcro screen wrap. Although these devices are fairly effective in preventing lateral movement, it is possible for the child to slide downward in the dental chair if he kicks in an attempt to escape, and in addition these devices are uncomfortable for the child due to their stiffness.

An object of the present invention is to provide an effective restraint system which is also comfortable and relaxing for the child patient. The invention is made of soft cloth, and has a first piece which has Velcro flaps which around the torso to comfortably restrain the patient, a headpiece which fits over the dental chair and straps which fit around the dental chair, and a second piece in which a cushion fits around the patient's buttocks and has flaps which fit around the patient's legs. Both the first piece and the second piece have an adhesive backing to prevent the patient from sliding in the dental chair.

Another object of the invention is to allow an adult size dental chair to be converted for use for any size patient, including children.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top perspective view of the front side of the restraint.

FIG. 2 is a top perspective view of the back side of the restraint.

FIG. 3 is a top and front perspective view of the cushion.

FIG. 4. is a top view of the device in use on a patient in the dental chair.

DESCRIPTION OF THE PREFERRED EMBODIMENT OF THE INVENTION

The invention is a combination restraint and cushion for use in holding a child patient comfortably in position on a dental chair. It is made of soft cloth material, with the various pieces cut from patterns and then assembled by sewing.

The restraint comprises a generally rectangular main body portion 1 which has a non-slip rubber backing 2 which adheres to the vinyl of the dental chair to create traction. Attached to the top of the main body portion 1 is a headpiece 3 which has a Lycra flap 4 which fits over the top of the dental chair. Two pair of horizontal flaps 5 are attached to the center of the main body portion 1 parallel to each other and extend beyond the outer edges of the main body portion 1. Each flap 5 is provided with hook and loop fastener (Velcro) pads arranged with the loop fastener 7 affixed to the bottom of one flap and the hook fastener 11 affixed to the top of the opposite flap 5, so that when the flaps 5 are folded inward over the patient's torso, the hook fastener 11

contacts the loop fastener 7, with the hook fastener 11 on top. A plurality of straps 12 are used to secure the restraint to the dental chair. One pair of straps 12 is attached to the headpiece 3 and ties around the head of the dental chair by connecting the hook fastener 11 affixed to the top of one strap 12 with the loop fastener 7 affixed to the bottom of the other strap 12. Another pair of straps 14 (or alternatively two pair) is attached to the main body portion 1 and ties around the armrests of the dental chair (or the back of the chair if there are no armrests) by means of hook and loop fasteners arranged such that each strap 14 has a hook fastener 11 at its proximal end and a loop fastener 7 at its distal end.

The cushion 15 is preferably about four inches thick, is generally rectangular with an arcuate indentation 17 at the top end which holds the child's buttocks and counteracts the effect of gravity by preventing the child from sliding downward in the dental chair. The cushion 15 is encased in a similarly shaped pillowcase 21 which has a zipper 33 to allow the cushion 15 to be removed for washing and which has a non-slip rubber backing 2 to adhere to the vinyl of the dental chair. A pair of flaps 22, having a hook fastener 11 on one and a loop fastener 7 on the other, is attached to the pillowcase 21 and folds together to hold the child's legs in position. If the dental chair lacks armrests, straps can be attached to the pillowcase 21 to be tied around the chair. The cushion 15 can be adjusted to accommodate different size children by overlapping it on the main body position 1 of the restraint to the length desired.

As an optional feature, a pair of Velcro strips may be provided on each of the pieces (loop Velcro on the top surface of the lower part of the main body portion 1 of the restraint and hook Velcro on the rubber backing 2 of the pillowcase 21 covering the cushion 15) so as to enable the cushion to not only be overlapped onto the restraint, but also to be attached to the restraint, thereby preventing sliding to an even greater extent.

Another optional feature is that slide locks or buckle closures may be used instead of Velcro to fasten straps 12 to the chair or to fasten straps 14 to the chair.

We claim:

1. 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 patient's torso in position, a plurality of 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.

* * * * *



VACHAREE S. PETERSON, D.D.S.
ANDREW F. PETERSON, D.D.S.
FAMILY DENTISTS

Oct. 7, 1997

To whom it may concern at the FDA:

This is to certify that the following 10 pages are copied from a textbook, titled *Behavior Management in Dentistry for Children*, written by Gerald Z. Wright, D.D.S., M.S.D., F.R.C.D.(C) and published by the W. B. Saunders Company of Philadelphia, USA. The book, printed in 1975, proves that the Olympic Papoose Board was sold commercially before May 1976. Please see pages 149 (bottom) and 150 (Fig. 8-2) which contain recommendations as to where to purchase the Olympic Papoose Board. This book was found in the University of Minnesota Dental School.

I am sending this exhibit in lieu of a statement from the Olympic Surgical Company of Seattle, Washington that their product, the Olympic Papoose Board, has been properly filed with the FDA. Despite our six attempts to reach them by telephone, fax and letter, they have refused to respond to our communications. However, this excerpt from the dental textbook mentioned above proves that the Papoose Board was sold before May 1976.

Yours Sincerely,

Vacharee Peterson, D.D.S.



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BEHAVIOR MANAGEMENT in DENTISTRY for CHILDREN

GERALD Z. WRIGHT
D.D.S., M.S.D., F.R.C.D. (C)

*Associate Professor
Department of Paediatric Dentistry
Faculty of Dentistry
The University of Western Ontario
London, Canada*



10-8-97

 LORI J. ANDERSON
NOTARY PUBLIC - MINNESOTA
MY COMMISSION EXPIRES
JANUARY 31, 2000



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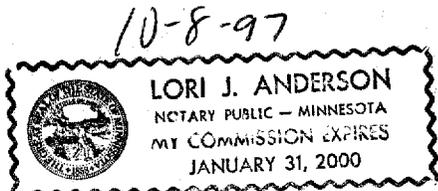
W. B. SAUNDERS COMPANY
PHILADELPHIA, LONDON, TORONTO

28



Chapter Eight

PHARMACOTHERAPEUTIC APPROACHES TO BEHAVIOR MANAGEMENT



Lori J. Anderson

[Signature]

This chapter is the result of the joint efforts of six pedodontists. Their purpose is to describe the pharmacologic agents most commonly used in pedodontics. The contributors to this chapter were selected because of their practical experience with these agents, as well as their ability to discuss theoretical aspects of the various drugs.

A sound underlying philosophy of the pharmacologic approach is: the dentist should limit himself to a few drugs so that he can maximize his experiences with these agents and thus gain a mastery of them. Most dentists do limit themselves to only a few drugs for managing the behavior of their child patients. Therefore, if a number of pharmacologic agents are to be described and their clinical applicability discussed, there is need for the multiple contributorship to this chapter. The contributors to this chapter adhere to a second basic philosophy: drugs are not substitutes for the fundamental nonpharmacotherapeutic approaches to behavior management. Rather, they are adjuncts which can aid the dentist in providing care for some of his more difficult child patients.

G.Z.W.

1. INTRODUCTORY REMARKS

Robert J. Musselman and David B. McClure

In 1973, a survey was conducted to determine the current pharmacologic means for managing children's behavior in pedodontics (Wright and McAulay, 1973). This survey provided the guide for the selection of drugs that are discussed in this chapter. It also shed light on both the general philosophies and the specific techniques of 409 pedodontists. For example, although 64 per cent of

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those surveyed used sedative drugs in their practices (excluding N₂O), the majority used them for less than 10 per cent of their patients. Obviously then, the management of many patients, who were referred as behavior problems to these specialists, was accomplished by fundamental nonpharmacotherapeutic approaches. Another finding was that the longer the pedodontists had been in practice, the less their tendency to use premedication. Although this finding may be explained in many ways, one possible explanation is that greater ability in the management of children's behavior was developed by these clinicians over the years.

Other questions in this survey were related to educational backgrounds. The results revealed that a higher percentage of pedodontists with previous postgraduate hospital training used drugs to sedate their patients than did pedodontists without extensive hospital experience. The relationship between the nature of the dentist's practice (the number of handicapped patients, the dentist's personality or the emphasis placed on drugs during his postgraduate studies) and his willingness to use drugs was not investigated. Nevertheless, that finding is understandable. Postgraduate programs, which include hospital training in anesthesiology, usually provide greater practical experience in monitoring vital signs and the normal fluctuations in pulse and respiration rates which may accompany medication. This clinical experience helps the pedodontist to gain confidence in maintaining airways, ventilating patients and administering other appropriate emergency measures.

The practitioner who has not had the opportunity for intensive emergency training in an undergraduate, postgraduate or continuing education program must be aware of his limitations. When he selects drugs for sedation, he should know their potentials, their advantages and their drawbacks. Before embarking on a new treatment modality in his practice, he must be totally familiar with the demands of that modality.

Drug Selection and Route of Administration. Decisions concerning the type of drug to be used and the suitable route of drug administration may be made, in part, on the basis of a child's cooperative behavior. Children may be placed in one of the following two categories:

1. Children who need preventive premedication.
2. Children who need management medication.

Children who need preventive premedication either have abnormal responses or are unnecessarily strained by the dental situation. They exhibit various forms of behavior. Some of this behavior has been described in Chapter Three as potentially cooperative. The children may be semicooperative in the dental operatory but have a low tolerance for the manipulations needed to complete their dental treatment. The timid child is an excellent example of this. He will cooperate while the dentist takes radiographs and may not prevent the dentist from performing a prophylaxis. However, he needs to be helped through the more demanding procedures. The behavior of a young, timid child may deteriorate into overt disruptive behavior during subsequent operative procedures if he is managed incorrectly. Preventive medication is one means of managing these potentially cooperative children.

The use of pharmacologic agents is not restricted to young patients. Older children, too, have concerns about dental procedures. However, their concerns may manifest themselves somewhat differently. Some older children may have difficulty sleeping the night before their dental appointments. Others tend to

react by becoming ill following office visits. These responses to dentistry need not occur. Although these children may be controlled without medication, in order to promote a positive dental attitude and to truly practice behavior management, some of them may also require preventive medication.

Kopel (1959) and Album (1955) both suggested that premedication should place children in a "quiescent state" and that the drug should prevent the dental treatment from disturbing this state by reducing the child's sensitivity. Preventive medication should be administered *orally* by the parent prior to the dental appointment. If the child has difficulty sleeping, it may also be given orally the night before the appointment.

The second categorization of children for drug usage includes those who need medication for behavior management. They cannot control their behavior in the dental office. Earlier in this text, they were described as lacking in cooperative ability. They may be mentally retarded, emotionally disturbed or so young that adequate communication between dentist and child is impossible. The dentist probably cannot obtain adequate radiographs of these children. Verbal communication may have little meaning for them. Thus, the dentist does not "get through" to these children. With experience, the dentist will learn to recognize these problems. Some of these children may require treatment in the hospital setting, but many can be attended to in the private office environment.

The very young child may be categorized as needing medication. Several questions can be asked of the parents of young patients which may alert the dentist to a possible management problem. How does the child behave in the physician's office? If the child is very disruptive every time he goes to the physician's office, then it can be expected that he will be difficult to manage in the dentist's office. Has the child ever been in the hospital? A hospital experience often causes the young child to be more apprehensive in the dentist's office. Does the child take a nap? If a two- or three-year-old child does not take a nap, the dentist should suspect that the child is very active, and he may require higher drug dosages to control his behavior in the dental office. How late does the child stay up at night? A preschool child who has the same bedtime as his parents may be more active or may not respond to discipline. Is the child toilet-trained? If a 2½-year-old child is not toilet-trained, the dentist may expect discipline problems in the dental office. Is the child strong-willed? A defiant child may struggle and shout in the dental office and refuse to "give-in" to the effects of medication.

Although medication is used for children under two years of age, its effect on these very young children can be highly unreliable. For this reason, some dentists prefer an alternative approach. A method such as gross caries excavation with band cementation demands less patient cooperation. In either case, with or without medication, the dentist should solicit the parent's help to restrain the child. The chairside position for this approach is illustrated in Chapter Twelve. If the mother is apprehensive (they usually are), then medication for her may be helpful. Under this circumstance, child and mother should be accompanied by another adult.

When dealing with two- to three-year-old children, as many as 40 per cent of those medicated for management may cry intermittently while being treated. The child's parents should be advised that the medication may not be as effective as we would like. Some dentists agree that it will help if the child is appointed at nap

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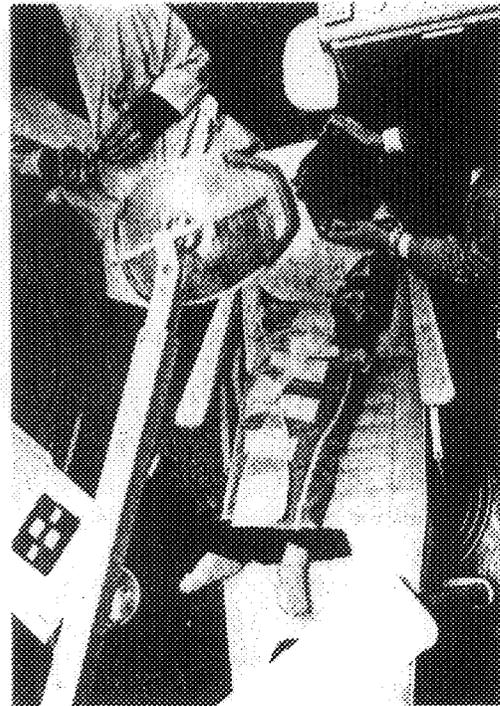


Figure 8-1 A medicated child restrained with a Pediwrap and with a Mohr type mouth prop placed. The dentist is instructing the assistant to tilt the child's head back to lift the chin and assure a patent airway.

time. On the day of the appointment the child should be awakened early and kept active all day until the appointment. The child can be brought to the dentist's office in pajamas and with a favorite toy. This will encourage him to sleep throughout the appointment.

Restraints. The dentist must be prepared to use restraining devices in conjunction with medication. Davis (1974) has described the use of the Pediwrap*, suggesting that the medicated child feels secure and comfortable when properly restrained (Fig. 8-1). Kroll (1969) reported the use of a similar type of body restraint in half of 75 treatment appointments for *emotionally, physically and mentally handicapped* children. He also used mouth props, "... routinely as a matter of convenience and control." Another type of restraining device is known as the Olympic Epopose Board. This device, which employs a body wrap and a board, can be placed on the dental chair (Fig. 8-2). The proper placement of these restraints keeps the periodic episodes of physical resistance which the sedated child may exhibit from disrupting his dental treatment.

The sedated child may react unfavorably either to being transferred to the dental operator or to the administration of a local anesthetic agent or to both. The use of restraints permits the rapid completion of these activities, after which the child will become cooperative and drowsy.

Although large dosages of medication may obviate the need for restraints

*Clark Associates, Worcester, Mass.

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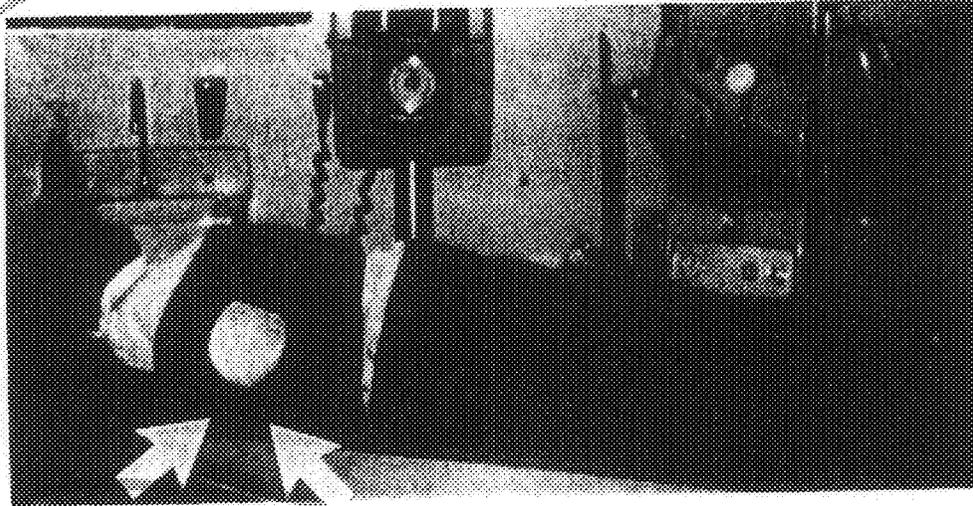


Figure 8-2. The rigid board helps to prevent spirming in the restraining device. (Photograph courtesy of Dr. Jay I. Reznick.)

during dental treatment, overmedication of the child increases the probability of undesirable and dangerous side-effects. Each dentist must adhere to a reasonable, safe, upper limit of the quantity of drug that he will administer. If that dosage does not control the child adequately, *even with restraints*, then the child should be considered a candidate for dental treatment under general anesthesia.

Oral Administration. When prescribing oral sedation agents, the form of the drug must be considered. The *elixir* form of the drug should be prescribed for young children who cannot swallow a tablet. Tablets can be used to premedicate older children. Sometimes they more readily accept a crushed or broken tablet in food or drink. This should be encouraged. Also, the dentist should prescribe a sufficient quantity of a drug to cover all of the required treatment appointments.

The dentist should not dispense any medication from his own supply without giving the parents written instructions. The amount of the drug and the time it should be given must be noted. A carbon copy of those instructions should be retained by the dentist so that office records accurately detail the instructions that were given. When multiple dosages are prescribed, it is better to give the parent a prescription to avoid confusion over dosage requirements.

Oral medication has these advantages: (1) the parent can administer the medication; (2) the medication can be administered prior to the dental appointment so that it will have reached an effective level at the time of the appointment; and (3) administration is not fear-producing. Disadvantages include the following: (1) reduced stomach and intestinal mobility, or food contents, may delay absorption of the drug—hence, the effect may be delayed or prolonged; (2) the dentist is dependent on the parent for administration; (3) the child may react unfavorably to the flavor or taste and may successfully resist taking the medication; and (4) many medications have reduced effects when taken orally.

Intramuscular Administration. Medication for management should be administered by the intramuscular route. Sometimes it is the sole method of seda-

tion, or it may be used in conjunction with other medications.

When using sedation in the office about operative visits, intramuscular sedation there will be a significant effect.

Intramuscular sedation has a (2) a good effect of an equivalent effect will have a significant effect. Supervise the child during the procedure.

Three sedation agents are used: oral or intramuscular and the deltoid muscle. A 26-gauge, 1-inch disposable syringe is used. The dose is equal to the child's weight before removal of the alcohol before being wiped with an antiseptic.



Figure 8-3. Administration of medication while patient is lying down.

PHARMACOTHERAPEUTIC APPROACHES TO BEHAVIOR MANAGEMENT

tion, or it may be used in combination with other drugs given orally. Oral medications often are given before the appointment.

When using management medication, the child should be brought to the office about one hour before his scheduled appointment. His behavior and pre-operative vital signs can be recorded by the dentist or his auxiliary. Following the intramuscular injection, the child can join his parent in a consultation room where there will be few distractions.

Intramuscular administration of the medication provides: (1) a more rapid effect, (2) a greater sedative effect and (3) an effect of shorter duration than that of an equivalent oral dosage. Within 30 to 45 minutes after the injection, the peak effect will have been reached. During this time, the dentist is able to monitor and supervise the child's condition.

Three sites are acceptable for intramuscular injections. These are the midlateral or anterior aspect of the thigh, the upper outer quadrant of the gluteal area and the deltoid area. The armamentarium for the administration consists of 25- or 26-gauge, 1 inch long disposable needle, which should be used with a 1 to 5 cc. disposable syringe. If a multiple dose drug vial is used, then an amount of air equal to the amount of solution to be withdrawn should be placed into the vial before removing the drug. The rubber stopper on the vial must be cleansed with alcohol before the injection. Similarly, the epidermal tissue injection site should be wiped with alcohol. The skin over the muscle should be tensed either by retract-

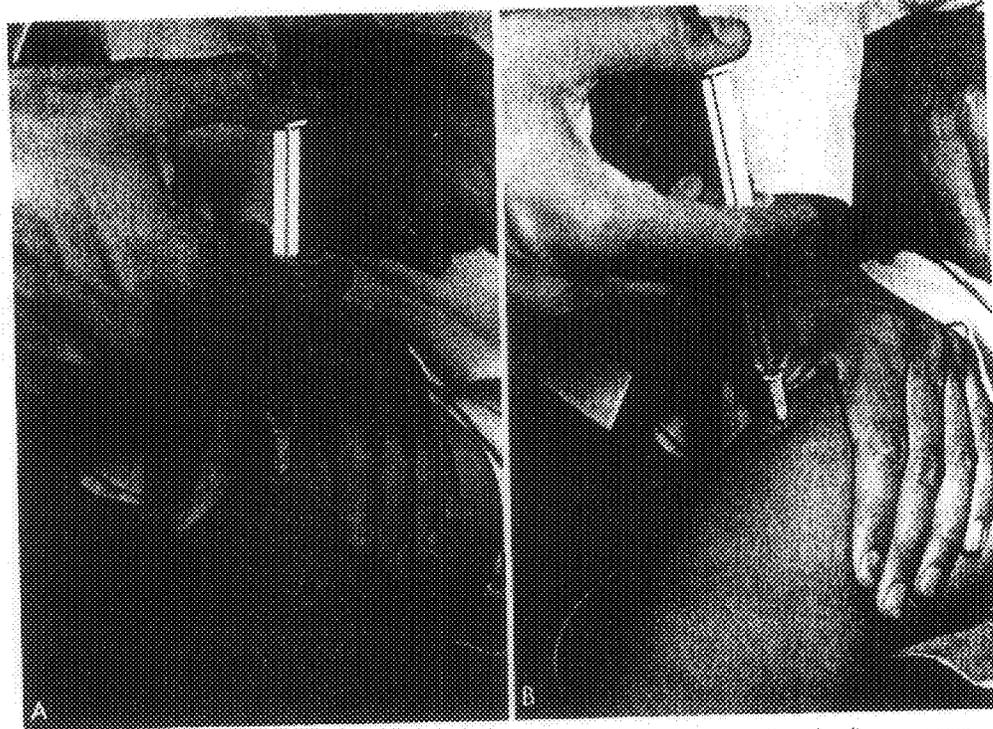


Figure 8-3 The skin at the injection site should be tensed by spreading the fingers apart while pushing down (A) or by squeezing up the muscle between the thumb and fingers (B)

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PHARMACOTHERAPEUTIC APPROACHES TO BEHAVIOR MANAGEMENT

BEHAVIOR MANAGEMENT

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was required for

ine (Nalline) or
y depression that
ulti-use vials, and

the dentist must have one ready for use whenever he is administering meperidine. An example of one of these drugs is shown in Figure 8-7.

Naloxone (Narcan) is a new narcotic antagonist which is effective in the reversal of respiratory depression induced by meperidine in adults. It may be administered intravenously, intramuscularly or subcutaneously. The initial dose is 0.4 mg. (1 cc.). An additional dosage can be administered in three minutes if adequate respiratory function has not returned. Very few side-effects have been reported, and the use of naloxone does *not* risk further respiratory depression as do the other antagonists. The effectiveness of naloxone in children has not been established.

Levallorphan tartrate (Lorfan) does *not* counteract mild respiratory depression caused by meperidine, and may increase it. It should be used only for the treatment of severe respiratory depression. The initial dose is 1 mg. (1 cc.), with one or two additional doses at 10- to 15-minute intervals not to exceed 3 mg.

The initial dose of nalorphine (Nalline) is 5 mg. (1 cc.). If an adequate increase in pulmonary ventilation has not occurred, another 5 mg. is administered in 10 to 15 minutes.

In summary, meperidine is an effective adjunct for behavior management. It is mainly indicated for children under eight years of age who demonstrate overt, disruptive behavior. Since meperidine is so highly potent, it should not be used by the dentist until he is thoroughly familiar with the drug and the management of its side-effects.

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narcotic antagonist
available in the dental
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TECHNIQUES OF BEHAVIOR MANAGEMENT

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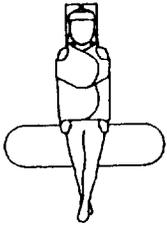
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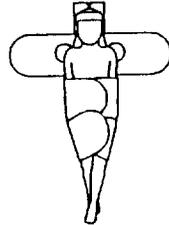
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Instructions for the Regular Size **OLYMPIC PAPOOSE BOARD**TM

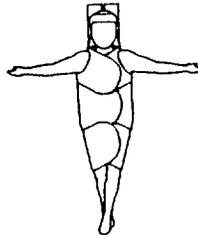
Positions



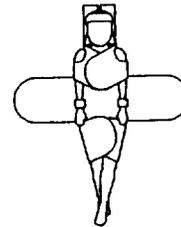
Legs Exposed



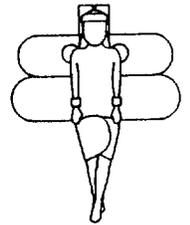
Chest Exposed



Arms Exposed



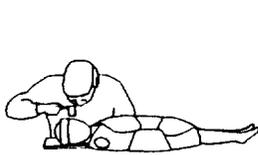
Abdomen Exposed



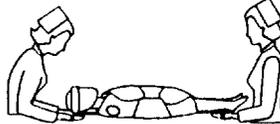
Upper Torso Exposed



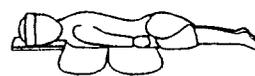
Patient standing



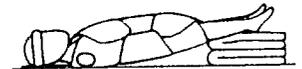
Ear and Eye



Moving Child



Prone Position



Trendelenburg

Cleaning Papoose Board

Canvas Flap Set and Arm Straps: Launder or spot clean with liquid disinfectant.

Papoose Board: Wipe clean with soap and water or liquid disinfectant.

Replacement Parts

Order extra flaps and straps so Papoose Board is always ready for immediate use. Call toll-free number on next page:

Canvas Flap Set, Cat. No. 50514
Head Strap, Cat. No. 50516
Arm Strap Set, Cat. No. 50520

Cautions

- This restraint should be used only when necessary for the safety and protection of the patient.
- It should be used only under the supervision of a licensed medical practitioner.
- It should be used only for temporary restraint when necessary for treatment. (Temporary restraint means that it should be applied only as necessary during a given medical procedure, and it should not be used for continuous or long-term patient restraint.)
- When restrained, the patient should be under continuous observation by a qualified medical practitioner.

- Particular attention should be paid to make sure that the restraint does not impair the patient's breathing, circulation, cause over-heating or positional injuries.

NOTE: Certain laws and regulations regarding the use of patient restraints have been published by federal and state agencies. Among these is the Omnibus Reconciliation Act of 1987 (OBRA). Guidelines for the use of patient restraints have also been issued by the Health Care Financing Agency (HCFA) and the FDA. These regulations do not forbid the use of patient restraints, but essentially state that restraints should be used only when necessary for the safety and protection of the patient and only under the direction of a medical authority. These guidelines should be followed when using the Olympic Papoose Board.

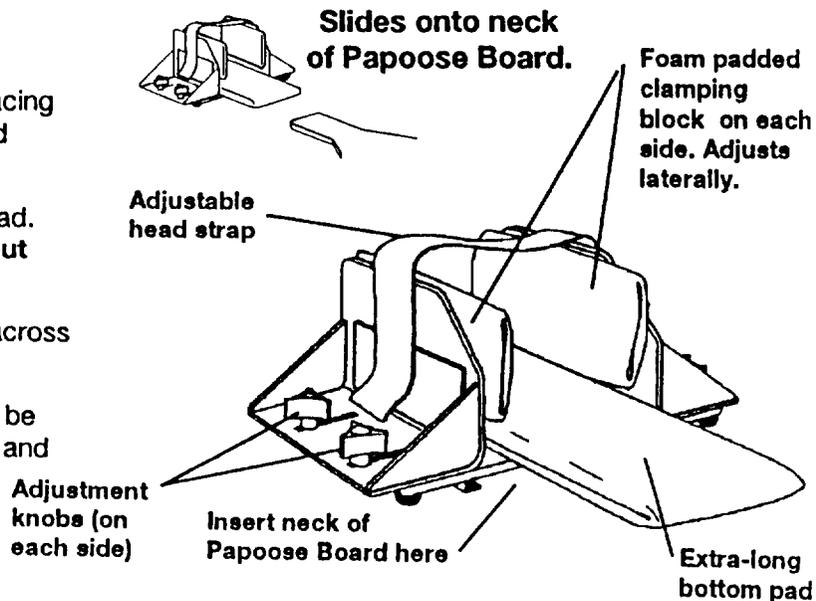


Accessories: The following accessories may be purchased for use with the Regular Size Olympic Papoose Board.

Head Immobilizer, Cat. No. 50508

1. Slide Head Immobilizer onto neck of Papoose Board.
2. Immobilize the child in the Papoose Board, placing the child's head between the two foam-padded blocks.
3. Slide the blocks laterally against the child's head. Adjust for a firm fit to hold head securely **without undue pressure**. Tighten adjustment knobs.
4. When necessary, fasten the soft Velcro strap across the child's forehead.

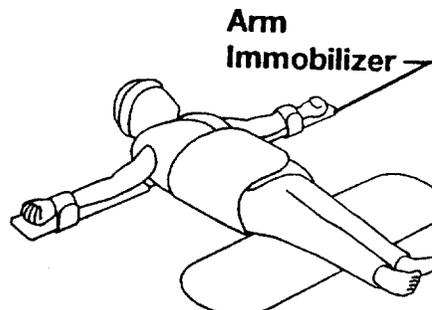
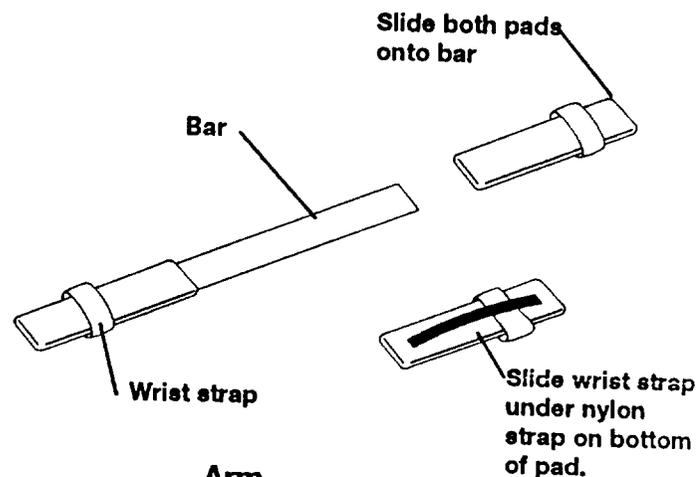
Cleaning: The head strap and all three pads can be removed for easy cleaning. Wipe clean with soap and water or liquid disinfectant.



Arm Immobilizer, Cat. No. 50506

1. Slide hand pads onto each end of Arm Immobilizer bar.
2. Slip a velcro wrist strap through the black strap on the bottom of each arm pad.
3. Place the Arm Immobilizer on the table.
4. Position the Papoose Board over the Arm Immobilizer, with the Arm Immobilizer approximately at shoulder height.
5. Position the child in the Papoose Board so that the arms are free (see "Arms Exposed" on other side).
6. Place the child's arms on the Arm Immobilizer and fasten the velcro wrist strap around each wrist.

Cleaning: Pads and wrist straps can be removed for easy cleaning. Wipe clean with mild disinfectant or soap and water.



Foam Pad, Cat. No. 50540

1. Foam Pad is installed on Papoose Board prior to positioning child.
2. Peel cover off adhesive strips on Foam Pad.
3. Press Foam Pad into place on top of the Papoose Board.

Information or Ordering

Call Toll-Free 1 800 426-0353

Questions? Contact CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

OLYMPIC MEDICAL

5900 First Ave S • Seattle, WA 98108 • USA
FAX (206) 762-4200

Dear Doctor:

A dentist who uses our Olympic Papoose Board developed a release form for parents to sign. We have duplicated the form on the next page. We thought it was a valuable, well-written document that you might be able to use to reassure your patients' parents whenever you have to use the Olympic Papoose Board. Please feel free to make as many copies as you need.

OLYMPIC  **MEDICAL**

Call Toll-Free 1-800-426-0353 (US and Canada)

5900 First Ave So • Seattle, WA • 98108 • USA

FAX 206-762-4200

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

OLYMPIC PAPOOSE BOARD

The Olympic Papoose Board is a safe restraining device to use in specific situations to hold a child still for dental procedures.

This device is found in emergency rooms to restrain a child who is uncooperative for necessary treatment. This would include injections or sutures. Likewise, in dental care, a child may not be manageable by conventional methods used. We do not use this as a punitive method, but as necessary for the child who cannot or will not cooperate. Dental care can then be done safely and comfortably, and once the restraint is in place, a child often relaxes.

This board is less alarming to a child than other forms of restraint. It lets the doctor and assistant be the provider of care, and not the antagonist trying to hold them to be still. It works by placing Velcro™ over the body in three sections, one or all of these can be used as needed.

An alternative to this is referral to a specialist, and hospitalization for sedation of the child.

OUR GOAL IS TO PROVIDE A SAFE DENTAL VISIT!

I recommend the use of this for your child, and ask your permission to use it.

Signature _____ Date _____

Respectfully Yours

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Exhibit VII

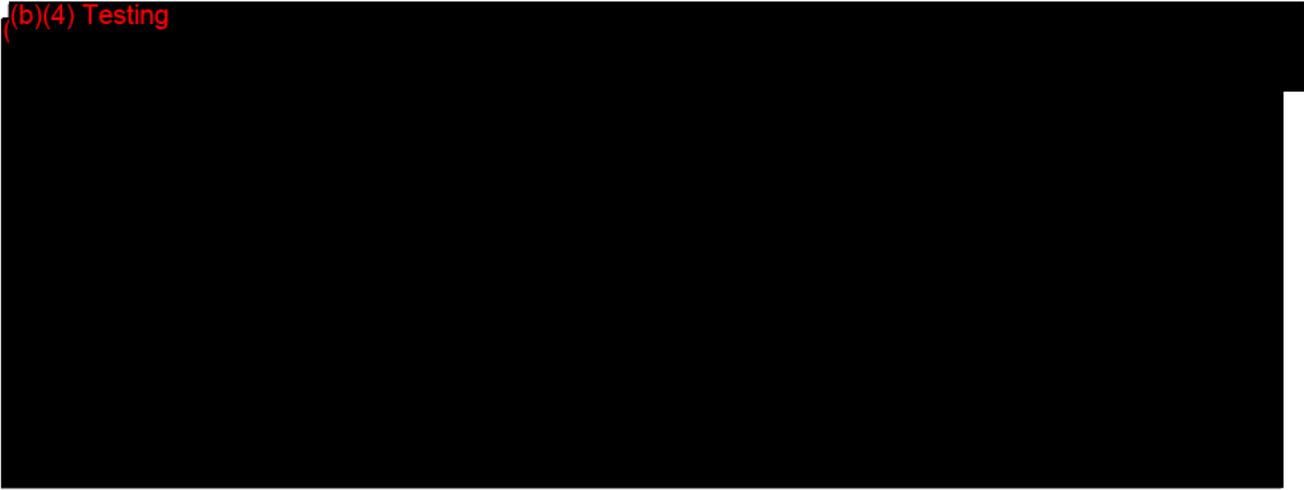
Released under FOIA Request # 2016-1365; Released by CDRH on 05-16-2016

(b)(4)



Summarized Data:
August, 1997

(b)(4) Testing



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 08, 1997

CAVITY FREE KIDS, INC.
1224 ARCADE ST.
ST. PAUL, MN 55106
ATTN: VACHAREE S. PETERSON

510(k) Number: K972446
Product: PEDO CUSH PEDO
CUDDLE

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date: 9/4/97
From: Reviewer(s) - Name(s) Irene Naveau

Subject: 510(k) Number K972446

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept). Telephone Hold
- Accepted for review 7/15/97
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

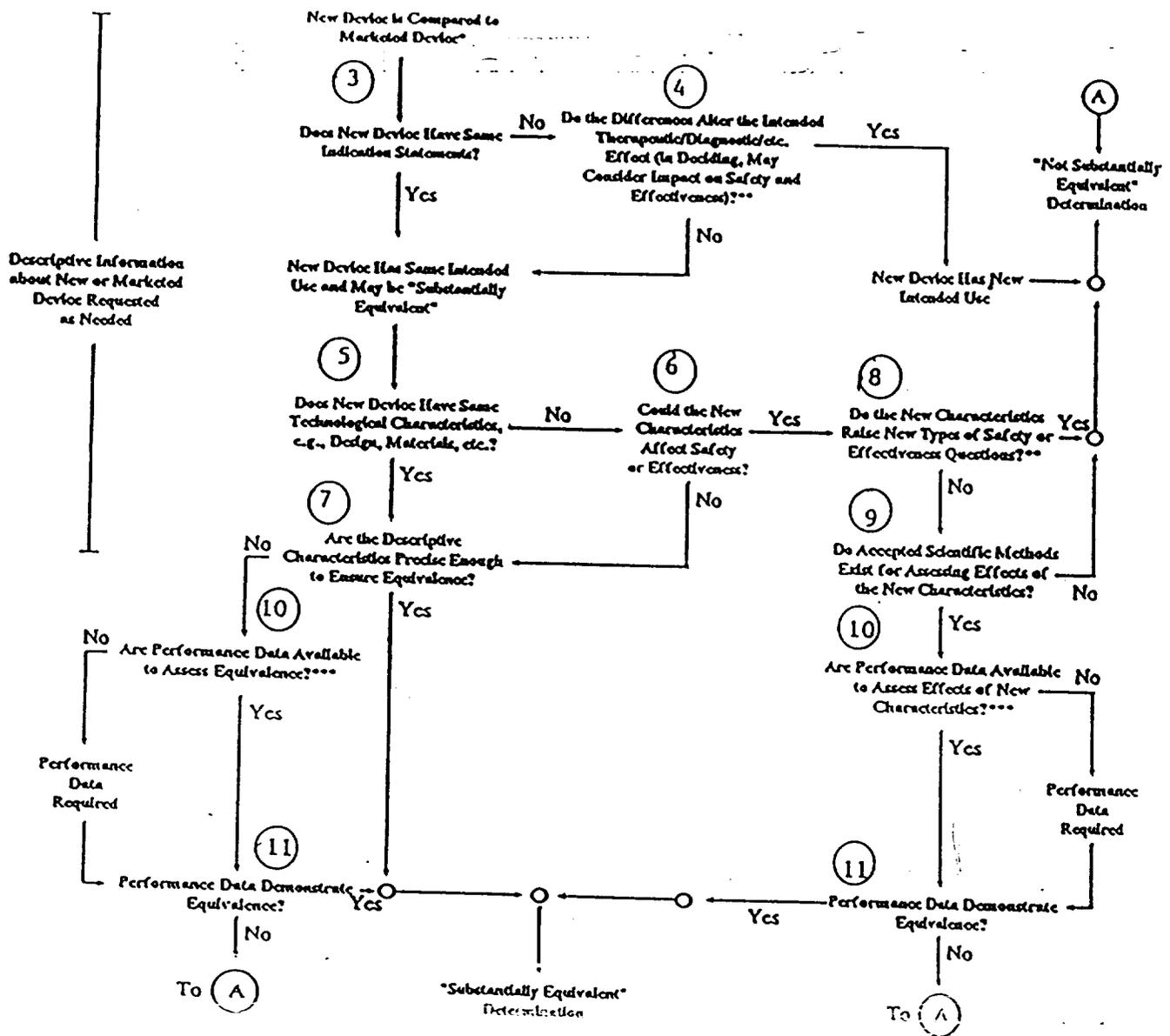
- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: Additional Product Code(s) with panel (optional):

Review: Patterson Cuvillo ONDB 9/4/97
(Branch Chief) (Branch Code) (Date)

Final Review: Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Date: September 4, 1997

Irene Naveau

HFZ-480

Review Record
K972446, Pedo Cush Pedo Cuddle

DDIG/GHDB

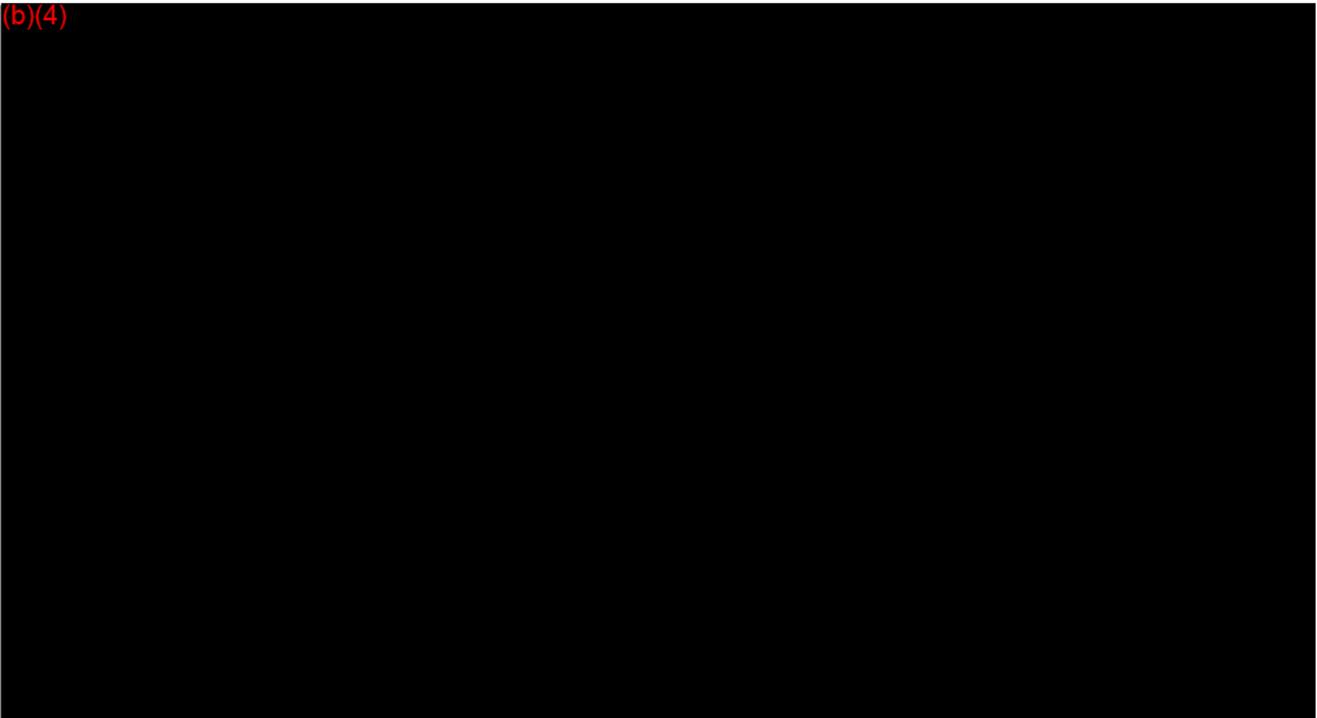
MEMORANDUM OF TELEPHONE CONVERSATION

Between: Irene Naveau, Nurse Consultant
DDIG/GHDB, HFZ-480

And: Dr. Vacharee Peterson/Dale Saxon, assoc./Katherine, assoc.
Cavity Free Kids, Inc.
(612) 774-0583

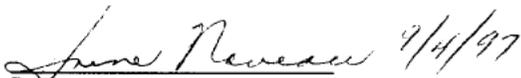
I communicated with Dr. Peterson and her associates on August 13, 22, and September 3, 4, 1997 regarding the above referenced 510(k). My questions and concerns on both parts include the following:

(b)(4)



Dr. Peterson stated that (b)(4) (b)(4) I informed her that I would place this 510(k) on telephone hold until such time that she was able to obtain the required information which would allow me to continue the review of this document.

RECOMMENDATION: TELEPHONE HOLD


Irene Naveau

K972446/A

July 7, 1997

Page ___ of ___

510(k) Number (if known): K972446

Device Name: PEDO CUSH PEDO CUDDLE

Indications For Use:

IN THE PRACTICE OF DENTISTRY WITH CHILDREN, THE PEDO CUSH PEDO CUDDLE WILL BE USED TO PROTECT THE CHILD FROM GRABBING INSTRUMENTS OR INJURING HIMSELF/HERSELF AS A RESULT OF OUT OF CONTROL BEHAVIOR. THE PEDO CUSH PEDO CUDDLE ADDITIONALLY PROVIDES PERSONAL SECURITY FOR THE CHILD KEEPING THEM FROM SLIDING OR SLIPPING IN THE DENTAL CHAIR.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

SK = 25

JP

Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
Checklist for Premarket Notifications [510(k)s]

Device Trade Name: PEDO CUSH PEDO CUDDLE		K#:K972446	
Submittal's Name: CAVITY FREE KIDS, INC.			
Date Received: 1 JUL 97			
90 Day Due Date: 28-SEP-97			
Review Tier : 1			
Question		Yes	No
A. Is the product a device?		X	
B. Is the device exempt from 510(k)?			X
C. Expedited Review Status: Requested by sponsor,			X
or identified by PILOT Division			
Granted by Pilot Division?			
D. Has this device been the subject of a previous NSE decision?			X
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?			
E. Has the sponsor been the subject of an integrity investigation?			X
If yes, has the ODE Integrity Officer given permission to proceed with the review?			

Decision: ACCEPT X REFUSE TO ACCEPT

Administrative Reviewer Signature: *Barbara J. Howard* Date: 1 JUL 97

Supervisory Signature: _____ Date: _____

Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
Screening Checklist for Premarket Notifications [510(k)s]
ELEMENTS ALWAYS REQUIRED MARKED WITH ASTERISK (*)

Device Name: PEDO CUSH PEDO CUDDLE		K972446
Submittal's Name: CAVITY FREE KIDS, INC.		
General Content of a 510(k)		MISSING INFORMATION
<p>1.* <u>General Information:</u> a) trade name, b) common name, c) establishment registration number, if known d) address of manufacturing sites, e) FDA assigned device class (I,II,III), f) FDA review panel, if known, g) state if submission is for a new device or modification of a legally marketed device, h) identify legally marketed device(s) to which applicant claims equivalence of submitted device, i) applicant's name and address.</p> <p>COMMENT:</p>		
<p>2.* <u>Safe Medical Device Act of 1990 Requirements:</u> a) 510(k) summary or statement (ALL devices) b) Truthful and Accurate Statement (see attached) c) Class III Certification & Summary (only for Class III devices). d) Indication for use statement</p> <p>COMMENT:</p>		D
<p>3.* <u>Proposed Labeling:</u> a) device and package labels, b) package insert, c) statement of intended use, d) promotional material that may accompany device.</p> <p>COMMENT:</p>		
<p>4.* <u>Description of Device (or modification):</u> diagrams, engineering drawings, or photographs.</p> <p>COMMENT:</p>		

<p>5.* <u>Comparison Information:</u> similarities and differences to named legally marketed equivalent device(s), a comparison table of attributes is recommended and should compare and contrast: a) labeling, b) intended use, c) specifications, d) materials, e) performance (bench, animal, clinical) data (as needed), f) analysis of comparable safety and effectiveness.</p> <p>COMMENT:</p>	
<p>6. <u>Biocompatibility Data:</u> needed for all direct or indirect patient or user-contacting materials per Tripartite Guidance or ISO standard, or provide a certification that materials are identical to legally marketed devices for same intended use.</p> <p>COMMENT:</p>	
<p>7. <u>Sterilization Information:</u> a) sterilization method, b) Sterility Assurance Level, c) type of packaging, d) pyrogen test method, e) EtO residues, f) radiation dose, g) statement of validation method.</p> <p>COMMENT:</p>	
<p>8. <u>Software Validation & Verification:</u> according to FDA guidance: a) hazard analysis, b) level of concern, c) development documentation, d) certification.</p> <p>COMMENT:</p>	
<p>9. <u>Information Recommended in FDA Guidance:</u> There is an FDA guidance document for this device that recommends additional data.</p> <p>COMMENT:</p>	
<p>10. <u>Kit Information:</u> see attachment if this device is a kit.</p> <p>COMMENT:</p>	

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 01, 1997

CAVITY FREE KIDS, INC.
1224 ARCADE ST.
ST. PAUL, MN 55106
ATTN: VACHAREE S. PETERSON

510(k) Number: K972446
Received: 30-JUN-97
Product: PEDO CUSH PEDO
CUDDLE

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

K972444

COVERSHEET

510 (k) NOTIFICATION

Date: 5-16-97

Applicant's name and address: Cavity Free Kids Inc.

1224 Arcade St.

St. Paul, MN 55106

Contact person: Dr. Vacharee S. Peterson

Telephone no.: (612) 774-0583

Fax no.: (612) 774-1997

Signature of applicant:



Address of manufacturing site: Angel Industries Sewing

488 S. Robert St.

St. Paul, MN 55107

Telephone: (612) 224-7591

FDA/CDRH/OCE/DHC

30 MAY 11 01

RECEIVED

SK-42

SK-42

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Labeling for Pedo Cush Pedo Cuddle	App. 1
Labeling for Pedi-Board	App. 2
U.S. Patent No. 5,425,381	App. 3



**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As Required by 21 CFR 807.87(j)]**

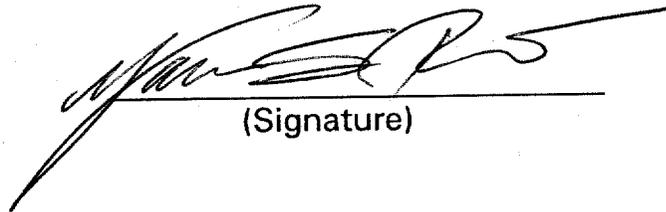
President/Owner

I certify that, in my capacity as (the position held in company) of
Cavity Free Kids

(company name), I believe to the best of my knowledge, that all data

and information submitted in the premarket notification are truthful and

accurate and that no material fact has been omitted.



(Signature)

Vacharee S. Peterson

(Typed Name)

5-16-97

(Date)

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to
submit the premarket notification [e.g., not a consultant for the
510(k) submitter].



DEVICE NAME

Trade name: Pedo Cush Pedo Cuddle

Common name: Protective Restraint

Classification Name: Protective Restraint (per 21 CFR §880.6760)

REGISTRATION NUMBER

No registration number has been obtained as yet.

CLASSIFICATION

Class I

Panel: General Hospital and Personal Use Devices

Product Code: 80FMQ

LABELING

Advertisement and instructions for use are included as Appendix 1.

STATEMENT OF INDICATIONS FOR USE

Its purpose is to protect the child from grabbing instruments or injuring himself/herself as a result of out of control behavior.

SUBSTANTIAL EQUIVALENCE COMPARISON

The legally marketed device to which equivalence is claimed is Pedi-Board Stabilizing System, manufactured by Specialized Care Co., Edison, NJ. This is a Class I device which has been granted marketing clearance by FDA following submission of a 510(k), document control number unknown.

Comparison of technological characteristics (Table 1)

PedoCush PedoCuddle	Pedi-Board
Intended use: To protect child from injuring himself/herself as a result of out of control behavior.	To protect both patient and clinician from sudden and unsafe patient movement.
Target population: Children	Same

Design:

Wrap and cushion each having 31 per 30147968118 Velcro

with Velcro closures.

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, headpiece has Lycra flap. Foam cushion enclosed in soft cloth pillowcase (with non-slip rubber backing) having soft cloth flaps with Velcro closures.

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 calmed 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: Can be laundered and bleached.

Same.

Safety: Secures patient firmly and comfortably 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.

Advertisement for Pedi-Board is included as Appendix 2.

DESCRIPTION

A combination restraint and cushion for securing a pediatric patient

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 patient's torso in position, a plurality of 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 No. 5,425,381 and is described in more detail therein. A copy of this patent is included as Appendix 3.

PERFORMANCE

Pedo Cush Pedo Cuddle has been tested on over 1,000 child patients with behavior ranging from uncooperative and fearful to hysterically out of control. It controlled side-to-side and up-and-down motion of patients in the dental chair and successfully calmed patients so that dental procedures could be performed.

BIOCOMPATIBILITY

The portion of Pedo Cush Pedo Cuddle which comes in contact with the patient is soft cloth material. No problems were reported in the clinical tests referenced above.

510(k) SUMMARY

- (1) Submitter's name: Cavity Free Kids

Address: 1224 Arcade St.

St. Paul, MN 55106

Phone no.: (612) 774-0583

Fax no.: (612) 774-1997

Contact person: Dr. Vacharee S. Peterson

Date summary prepared: May 16, 1997

- (2) Trade name: Pedo Cush Pedo Cuddle

Common name: Protective Restraint

Classification Name: Protective Restraint (per 21 CFR §880.6760)

- (3) Identification of legally marketed device to which equivalency is claimed:

Pedi-Board Stabilizing System, manufactured by Specialized Care Co., Edison, NJ.

- (4) 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 patient's torso in position, a plurality of 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

89

Pedo Cush Pedo Cuddle is covered by U.S. Patent No. 5,425,381 and is described in more detail therein.

(5) Intended use: To protect both patient and clinician from sudden and unsafe patient movement.

(6) Comparison of technological characteristics:

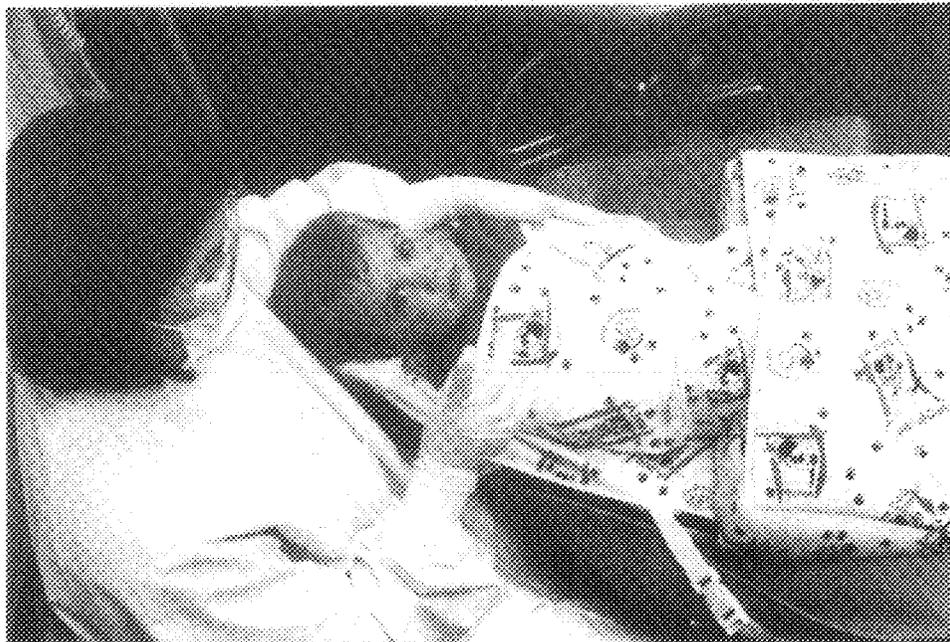
	Pedo Cush Pedo Cuddle	Pedi-Board
Design:	Wrap and cushion, each having flaps with Velcro closures.	Wrap with Velcro closures; board and head stabilizer can be added.
Materials:	Wrap (including flaps, straps, and headpiece) made of soft cloth with non-slip rubber backing, has Velcro closures, headpiece has Lycra flap. Foam cushion enclosed in soft cloth pillowcase (with non-slip rubber backing) having soft cloth flaps with Velcro closures.	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 calmed 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:	Can be laundered and bleached.	Same.
Safety:	Secures patient firmly and comfortably in dental chair.	Same.
Anatomical sites:	Secures patient's torso and legs.	Same.
Human factors:	Comfortable and relaxing for patient.	Same.
Compatibility with	Can be used with any standard dental chair.	Same.

Other devices: Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118
Where used: Dental office. Same.

Treating Young Patients?

Ease Your Tension and Protect Them with the

PEDO CUSH / PEDO CUDDLE™



**The First Securing Device
for Children Made
Specifically for Dentistry**

The PEDO CUSH / PEDO CUDDLE™ was made with the *dentist*, the *dental chair*, the *parent*, and most of all, the *child* in mind.

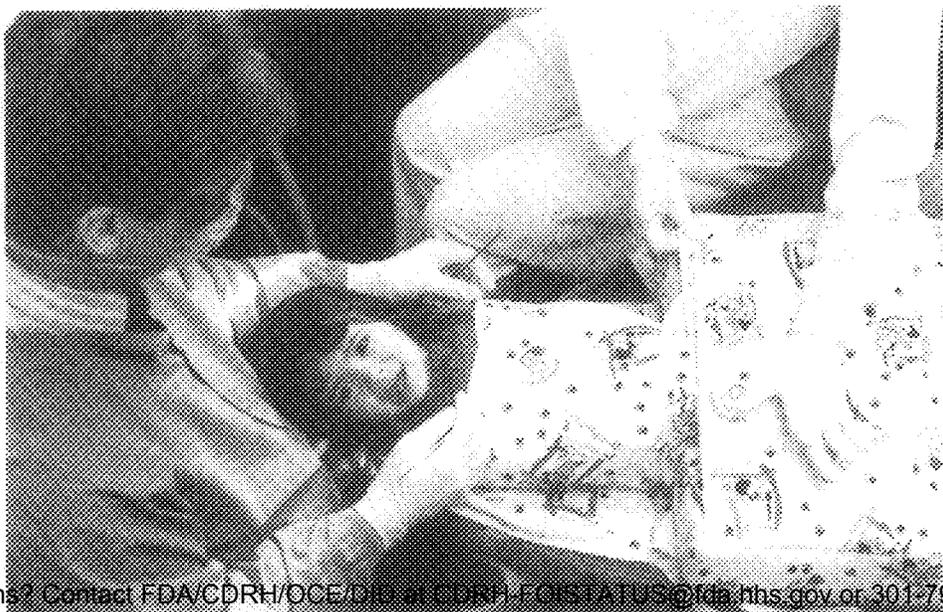
Adapts an Adult Dental Chair into a Child's Dental Chair

- Keeps children from sliding up and down.
- Provides the most comfort possible for children.
- Bright and cheerful, looks and feels inviting!



Provides Additional Security When Needed

A non-intimidating means of securing a child that provides for his/her safety in seconds. *Just pull up the flaps and you are set.* If you find that during the procedure this measure of security is not needed, *simply undo the flaps...* No hassles... Provides for your patient's safety and allows you to get on with dentistry.



The PEDO CUSH / PEDO CUDDLE™ has been tested on over 1,000 children with behavior ranging from *uncooperative and fearful* to *hysterically out-of-control*.

A MUST FOR EVERY DENTAL PRACTICE THAT TREATS CHILDREN!

- Converts an adult dental chair into a comfortable pedo dental chair in seconds!
- Positions the child correctly for dental treatment, preventing sliding up and down on the chair.
- Stabilizes the child by wrapping and securing with velcro. Warm and reassuring, the PEDO CUSH / PEDO CUDDLE™ is not intimidating like some restraints. The child feels safe.
- Prevents uncontrollable hitting and kicking when used appropriately.
- Educates parents about gentle restraint through a unique *Informed Consent Form*. Parents are more receptive to behavioral management techniques when they understand all the options and the reasons for them. And treating children is always less stressful when the parent and dentist are working together.

Comes with instructional video and Informed Consent Form.

Order Form

Name _____

Address _____

Phone # _____

Item	Quantity	Price Each
Pedo Cush/Pedo Cuddle	_____	\$199.95
Replacement Foam Pad Inserts	_____	\$25.00
Replacement Covers	_____	\$140.00
	Subtotal	_____
	Postage	_____
	Sales Tax	_____
	Total	_____

Mail to: Cavity Free Kids
1220 Arcade St.
St. Paul, MN 55106

Please allow 4-6 weeks for delivery.
Make checks payable to *Cavity Free Kids*

Questions? Comments? For more information call 612-774-0583

**Wrap your little patients in security
Cushion them in comfort with Podo Cush / Podo Cuddle™**



DENTAL PRODUCTS DESIGNED WITH CHILDREN IN MIND

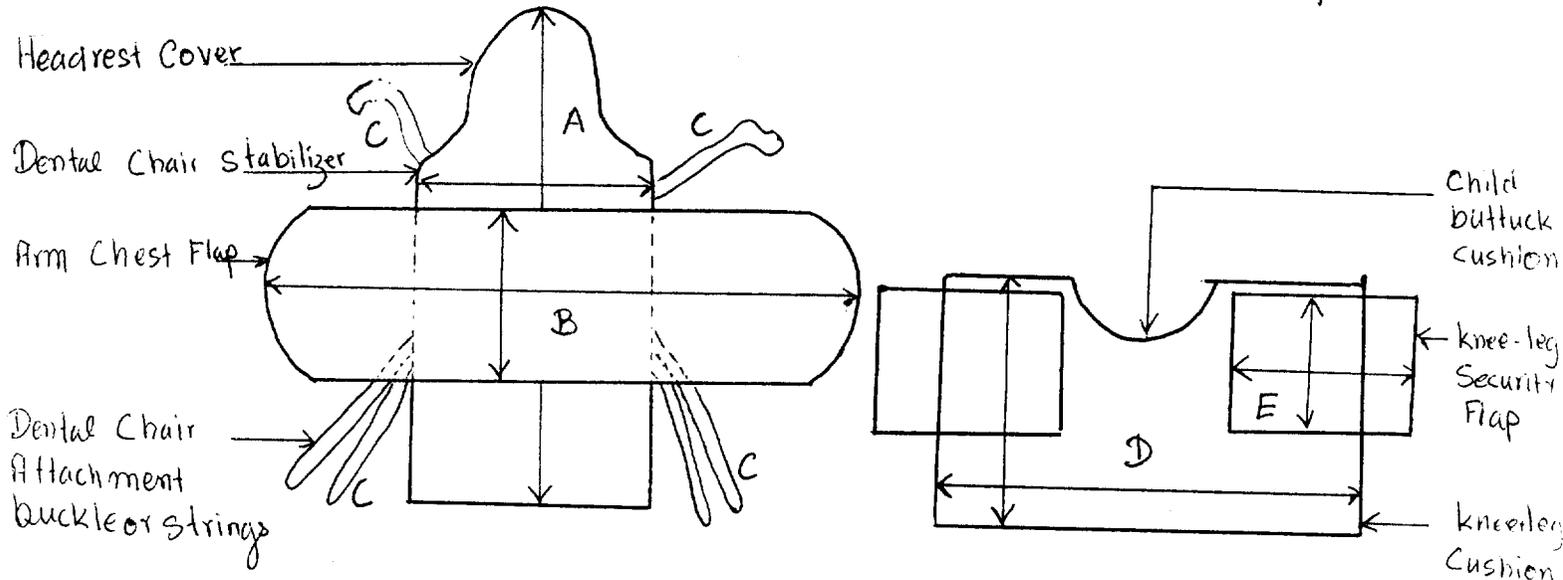
Cavity Free Kids
1220 Arcade St.
St. Paul MN 55106
612-774-0583

BULK RATE
U.S. POSTAGE
PAID
St. Paul, MN
Permit No. 8026

Dedicated to healthy teeth and bright smiles!

Pedo Cush Pedo Cuddle

Dental Child Security Device Dimensions and Components



Pedo Cuddle (Body-Arm Protector) Pedo Cush (Leg Protector)

Pedo Cuddle (Body-Arm Protector)

Size	Binding Color Code	Part A		Part B	
		Height	Width	Height	Width
XS	White	29"	15"	12"	29"
S	Red	30"	15"	15"	34"
M	Green	30"	15"	16"	39"
L	Blue	30"	15"	18"	46"

Leg Protector

One Size		
Part D	Part E	
Height	18"	11"
Width	19½"	11¼"
Part C	1" x 24"	

Size/Age Recommendations for Pedo Cush Pedo Cuddle

Size	Ordering Code Number	Approximate Age
Extra Small	PC - XS	6 months - 2 year
Small	PC - S	2 year - 4 year
Medium	PC - M	4 year - 6 year
Large	PC - L	6 year - 8 year

Handwritten initials/signature.

Pedo Cush Pedro Cuddle Instructions for Use and Care

Thank you for purchasing the Pedro Cush Pedro Cuddle. We want to ensure you every success in using this product. Please follow the directions below for the best results.

Prior to placing the child in the chair for treatment

1. Obtain informed consent from parent or person accompanying the child for treatment
2. Place the Pedro Cuddle on the dental chair in the following manner.
 - a. Slide the lycra head flap over the head rest of the dental chair. Adjust to desired fit by snapping the slide lock closures shut and pulling adjustable strap.
 - b. If your dental chair has arms secure slide lock straps around each arm and adjust. If your dental chair has no arms the slide lock straps may be taken around and fastened at the back of the dental chair.
3. Place child in the dental chair and position in the best manner for you to do dentistry.
4. Slide the Pedro Cushion up under the child's legs with the concave portion around the child's buttocks.

If you need to physically secure the child during treatment you may do so by simply pulling up the velcro flaps. The 1st set should be approximately 4-6 inches from the top of the shoulder. The second set should be placed in relation to the size of the child and the anxiousness of the child. The leg flaps that are cushioned should encompass the knees and protect the shins.

It is important to note that as the patient's behavior changes the amount of securing you need to do will also change. The Pedro Cush Pedro Cuddle should not be used as a form of punishment, or in an attempt to have power over the patient. Its purpose is to protect the child from grabbing instruments or injuring himself/herself as a result of out of control behavior.

We always encourage the participation of the parent in treating the child. A gentle massage and soothing words of the parent can often offer reassurance to the child and in fact make your job easier.

Never leave a child unattended in the Pedro Cush Pedro Cuddle or at anytime during dental treatment.

Laundering Instructions

The Pedro Cush Pedro Cuddle may be washed and bleached as often as needed by following these directions (also see care instruction tag on device)

1. Remove the cushion from the Pedro Cushion by unzipping the cover and removing the foam insert.
2. Machine wash warm, bleach as necessary. Tumble dry, and reinsert cushion.

It is our sincere hope that you find this to be a useful product. You may refer to the video tape for further instructions on how to put on your chair. If you are not satisfied with your



purchase please return item for full refund and explanation of problem. We do value your patronage and your comments

Sincerely,

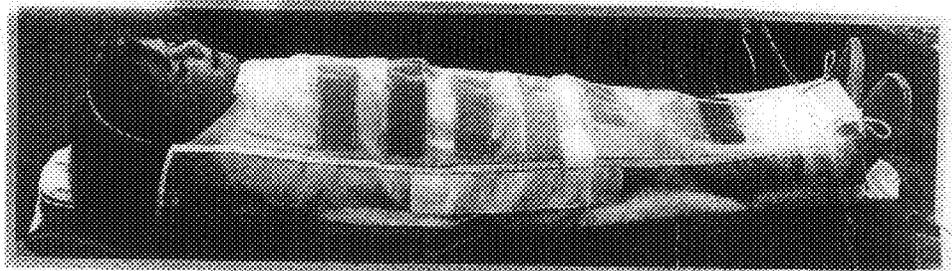
Catherine Boler
Coordinator
Cavity Free Kids.

Specialized Care Co.

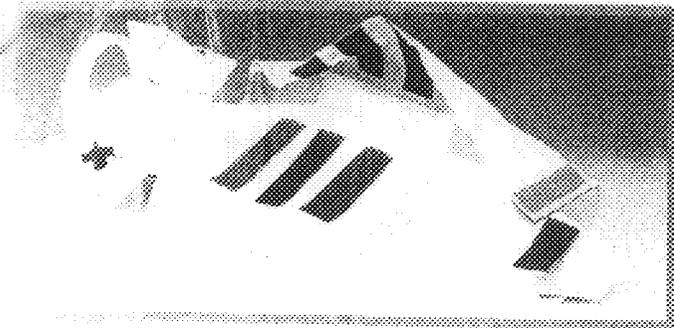
PEDI-BOARD™ STABILIZING SYSTEM

...Strong, breathable, patient friendly.

The PEDI-BOARD™ PATIENT STABILIZING SYSTEM provides shoulder-to-ankle coverage, protecting both patient and clinician from sudden and unsafe patient movement.



The most distinctive part of the Specialized Care Company Stabilizing system is the cool, breathable mesh wrap with colorful closures. Unlike heavier fabrics, the mesh allows body heat to escape, thus preventing overheating. Yet, it is remarkably effective at controlling unsafe patient movement. The multi-colored Velcro® closures give a friendly



Shown: A Small Stabilizing System, with a Head Stabilizer.

When additional support is required, the Specialized Care Co. Stabilizing Board can be quickly added to the wrap. The board is padded for comfort, and is covered with vinyl for easy cleaning. The board comes with a pillow which can be used to keep the patient's head tilted back for better oral access. Two pillows can be stacked to accommodate larger patients. It is advisable to secure the patient to the chair with our 5' safety belt, which wraps around the chair and the system.



look, and command greater acceptance by patients, parents and caregivers. Unusually long Velcro® tabs accommodate a wide range of patients, and allow for quick and easy closure. The wrap also has built-in wrist cuffs to keep the patient's hands out of harm's way.

The Specialized Care Co. Head Stabilizer helps to control side-to-side and up-and-down motion, and has padded, tapered side panels which allow for "four-handed" dental procedures. The Head Stabilizer is easily attached to the board with screws.

There are three sizes of boards, and five sizes of wraps to accommodate most patients. Call us today for assistance with sizing and prices. We're here to help!

Specialized  Care Co.

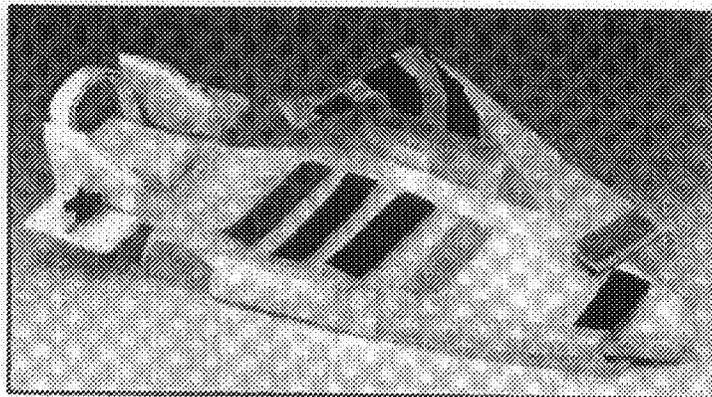
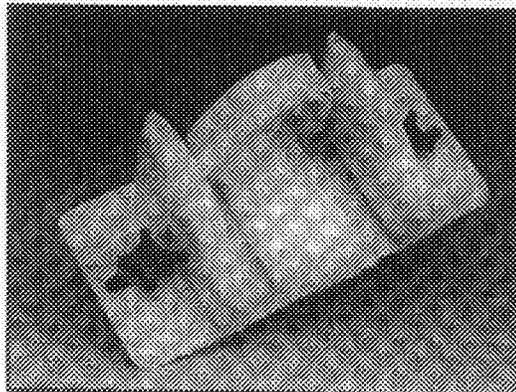
Dedicated to improving the oral health of people with special needs.

Important: Consult the appropriate authority in your state for regulations on the use of stabilizing devices.

15 Rence Court, Edison, NJ 08820-3634 USA
800-722-7375 OR 908-906-6631 FAX 908-494-8327

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 Specialized Care Co.

The Specialized Care Co. Patient Stabilizing System HEAD STABILIZER



When you need to minimize head movement during dental procedures, the Specialized Care Co. HEAD STABILIZER can be of significant value. Its two adjustable side panels help reduce side-to-side motion, and its head strap helps reduce up-and-down motion. It attaches directly and securely to any Specialized Care Co. stabilizing board.

The HEAD STABILIZER is available in two sizes, and adjusts to accommodate most patients. Both side panels are padded for comfort, and are tapered at the front to enhance oral access and to allow for "four handed" dental procedures.

The HEAD STABILIZER also comes with a pillow for added patient comfort. The vinyl pillow and padded side panels, as well as the durable plastic molded base and side pieces can easily be cleaned with a surface disinfectant.

Please call or write to us for more information, or to place an order.


Specialized Care Co.

Dedicated to improving the oral health of patients with special needs

15 Renee Court. Edison, NJ 08820-3004 USA

800•722•7375 908•906•6631 Fax: 908•494•8327

OK



Dedicated to improving the oral health
of people with special needs

800•722•7375

908•906•6631 Fax: 908•494•8327

PRICE LIST

April, 1996

All prices are in U.S. dollars

The **Specialized Care Co. Patient Stabilizing System**, with a padded board and a mesh wrap, is the most flexible and comfortable system available. The mesh wrap is breathable to reduce patient overheating, and the soft, padded board provides greater patient comfort. All pieces can be cleaned with a surface disinfectant or laundered with bleach.

Great flexibility! Buy one board and multiple wraps to accommodate a range of patients, and to reduce downtime due to laundering. When you need only minimal stabilization, use the SCC Wrap alone. For greater support, add an SCC Board. The Head Stabilizer attaches directly to the SCC Board to help prevent unwanted head movement.

The **SCC PATIENT STABILIZING SYSTEM** includes the board, wrap, wrist cuffs, a pillow and head strap. The SCC Mesh Wrap, when ordered alone, comes with wrist cuffs. The Head Stabilizer and Safety Belt are sold separately.

SCC PATIENT STABILIZING SYSTEMS

Code	Description	Approx. Ages	Price
PBS-S	small SCC Board, small SCC Wrap	Infants	\$160.00
PBS-M	small SCC Board, medium SCC Wrap	2-4 Years	\$170.00
PBM-M	medium SCC Board, medium SCC Wrap	4-7 Years	\$215.00
PBM-L	medium SCC Board, large SCC Wrap	7-10 Years	\$230.00
PBL-L	large SCC Board, large SCC Wrap	10-13 Years	\$260.00
PBL-XL	large SCC Board, extra large SCC Wrap	13-15 Years	\$285.00
PBL-XXL	large SCC Board, XXL SCC Wrap	16 and Older	\$295.00

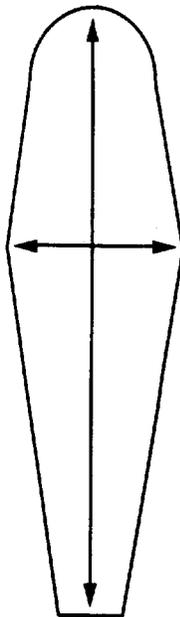
INDIVIDUAL UNITS

Code	Description	Price
SPWS	small SCC Wrap	\$ 85.00
SPWM	medium SCC Wrap	\$ 95.00
SPWL	large SCC Wrap	\$110.00
SPWXL	extra large SCC Wrap	\$135.00
SPWXXL	extra extra large SCC Wrap	\$145.00
SPBS	small SCC Board	\$ 75.00
SPBM	medium SCC Board	\$120.00
SPBL	large SCC Board	\$150.00
HIC-S	small HEAD STABILIZER	\$ 93.50
HIA-L	large HEAD STABILIZER	\$ 93.50
NP	extra Neck Pillow (with extra micro patch)	\$ 6.00
WC	extra Wrist Cuffs (per pair)	\$ 5.00
SB	5 ft. long adjustable safety belt (fits around patient & chair)	\$ 15.00

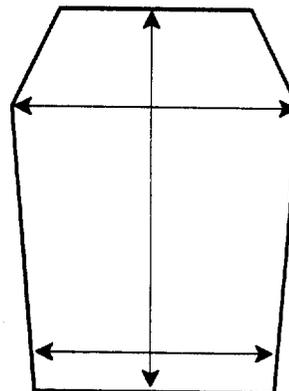
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"RAINBOW" STABILIZING SYSTEM DIMENSIONS

SCC BOARD



PEDI-WRAP®



SIZE	HEIGHT	WIDTH
Small	36"	11 1/2"
Medium	49"	12"
Large	59 1/2"	13"

SIZE	HEIGHT	WIDTH	
		Chest	Base
Small	26 3/4"	32"	22 3/4"
Medium	38 1/2"	35"	27"
Large	42 1/2"	41"	32 1/2"
X-Large	55"	48"	35"
XX-Large	55"	53"	35"

Size/age recommendations for "RAINBOW" Stabilizing Systems

CODE	SCC BOARD	PEDI-WRAP	APPROX. AGES
PBS-S	Small	Small	Infants
PBS-M	Small	Medium	2-4 Years
PBM-M	Medium	Medium	4-7 Years
PBM-L	Medium	Large	7-10 Years
PBL-L	Large	Large	10-13 Years
PBL-XL	Large	Extra Large	13-15 Years
PBL-XXL	Large	Extra Extra Large	16 and older

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



US005425381A

United States Patent

[11] Patent Number: **5,425,381**

Peterson et al.

[45] Date of Patent: **Jun. 20, 1995**

[54] **PEDIATRIC RESTRAINT AND CUSHION**

[76] Inventors: **Vacharee S. Peterson; Catherine T. Boler**, both of 1224 Arcade St., St. Paul, Minn. 55106

3,565,419	2/1971	Allard	5/633
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5,129,406	7/1992	Magnusen	128/873

[21] Appl. No.: **349,243**

*Primary Examiner—Michael A. Brown
Attorney, Agent, or Firm—Thomas B. Tate*

[22] Filed: **Dec. 5, 1994**

[51] Int. Cl.⁶ **A61B 19/00**

[57] **ABSTRACT**

[52] U.S. Cl. **128/809; 128/876**

[58] Field of Search **128/345, 846, 869-876;
5/630, 632, 633, 636, 647, 648, 623, 653, 424**

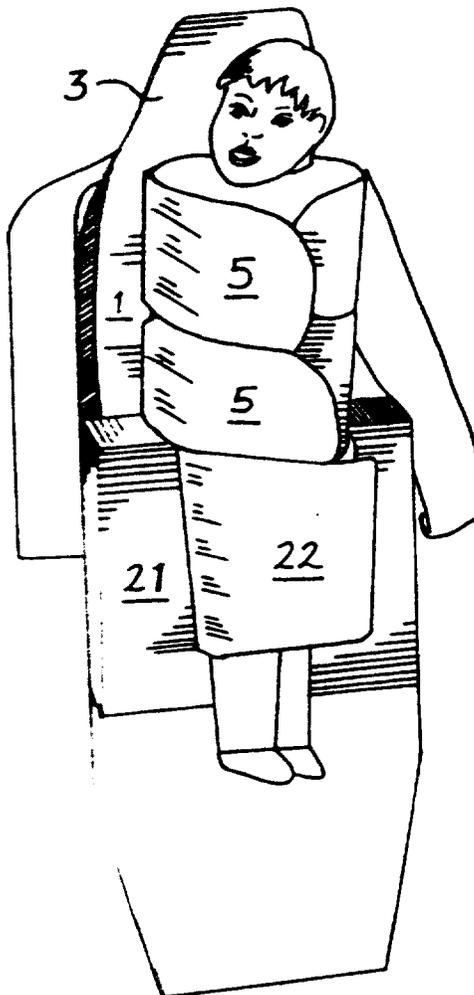
A combination pediatric restraint and cushion for a dental patient. The restraint is made of cloth with an adhesive backing, and has a plurality of flaps with hook and loop fasteners, a plurality of straps, and a headpiece. The cushion is encased in a pillowcase which has an adhesive backing and has flaps with hook and loop fasteners, and has an arcuate indentation at its top end.

[56] **References Cited**

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1 Claim, 4 Drawing Sheets



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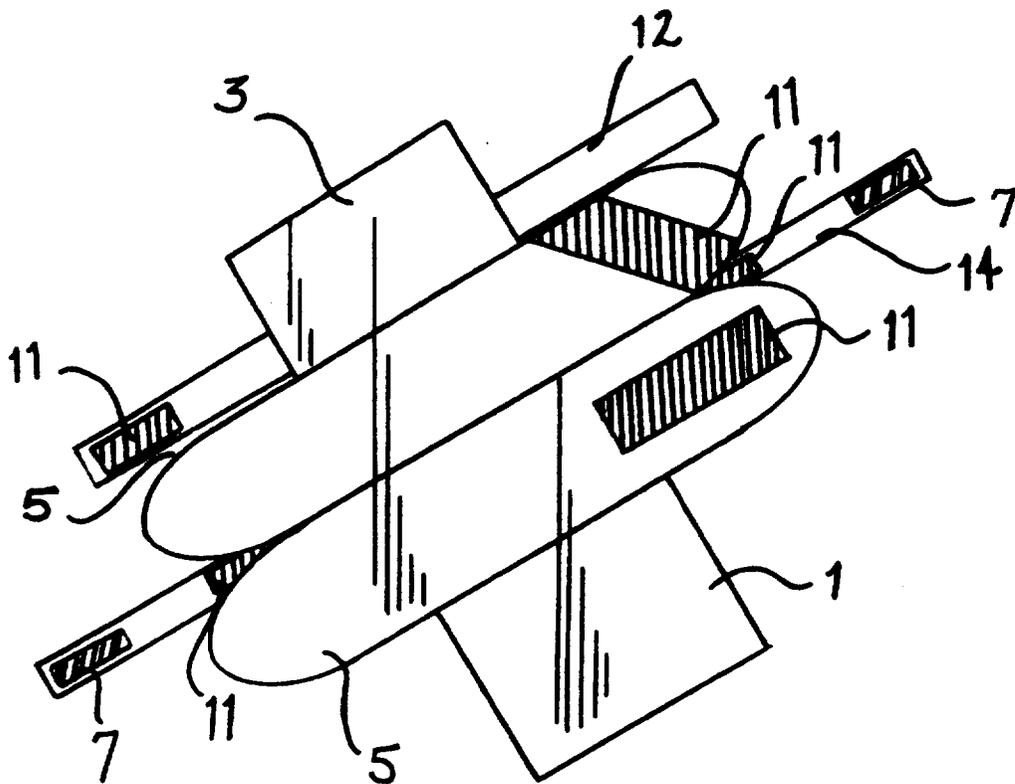


FIG. 1.

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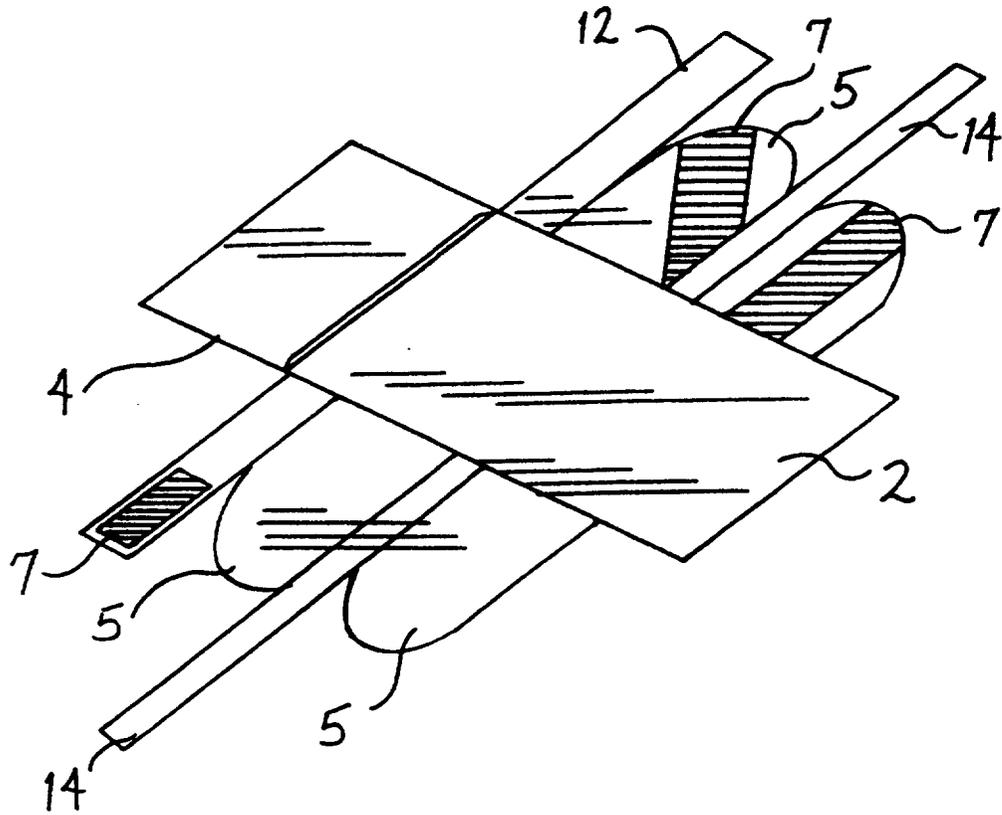


FIG. 2.

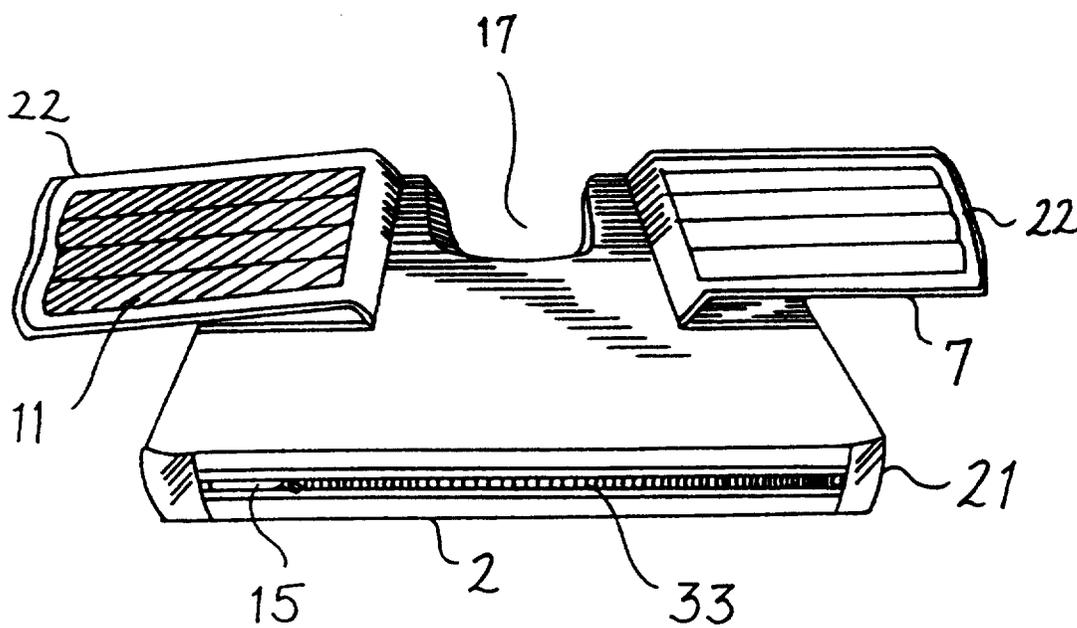


FIG. 3.



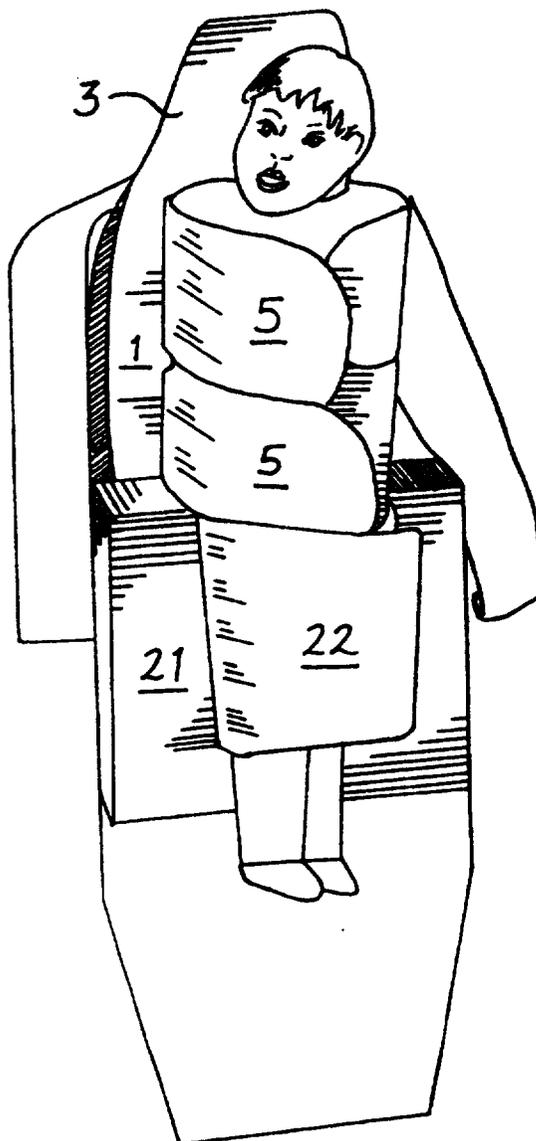


FIG. 4.

PEDIATRIC RESTRAINT AND CUSHION

SUMMARY AND BACKGROUND OF THE INVENTION

When a pediatric dental patient is restless and uncooperative, it is often necessary for the dentist to use a restraining device to hold the child in position in the dental chair long enough for the dentist to complete the necessary work. The two devices most commonly used for this purpose are the Olympic Papoose Board manufactured by Olympic Medical, which is a Velcro wrap which has armholes and a stiff board upon which the child's back rests, and the Pedo-Wrap manufactured by Clark Associates, which is a stiff pillow device with a mesh and Velcro screen wrap. Although these devices are fairly effective in preventing lateral movement, it is possible for the child to slide downward in the dental chair if he kicks in an attempt to escape, and in addition these devices are uncomfortable for the child due to their stiffness.

An object of the present invention is to provide an effective restraint system which is also comfortable and relaxing for the child patient. The invention is made of soft cloth, and has a first piece which has Velcro flaps which around the torso to comfortably restrain the patient, a headpiece which fits over the dental chair and straps which fit around the dental chair, and a second piece in which a cushion fits around the patient's buttocks and has flaps which fit around the patient's legs. Both the first piece and the second piece have an adhesive backing to prevent the patient from sliding in the dental chair.

Another object of the invention is to allow an adult size dental chair to be converted for use for any size patient, including children.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top perspective view of the front side of the restraint.

FIG. 2 is a top perspective view of the back side of the restraint.

FIG. 3 is a top and front perspective view of the cushion.

FIG. 4. is a top view of the device in use on a patient in the dental chair.

DESCRIPTION OF THE PREFERRED EMBODIMENT OF THE INVENTION

The invention is a combination restraint and cushion for use in holding a child patient comfortably in position on a dental chair. It is made of soft cloth material, with the various pieces cut from patterns and then assembled by sewing.

The restraint comprises a generally rectangular main body portion 1 which has a non-slip rubber backing 2 which adheres to the vinyl of the dental chair to create traction. Attached to the top of the main body portion 1 is a headpiece 3 which has a Lycra flap 4 which fits over the top of the dental chair. Two pair of horizontal flaps 5 are attached to the center of the main body portion 1 parallel to each other and extend beyond the outer edges of the main body portion 1. Each flap 5 is provided with hook and loop fastener (Velcro) pads arranged with the loop fastener 7 affixed to the bottom of one flap and the hook fastener 11 affixed to the top of the opposite flap 5, so that when the flaps 5 are folded inward over the patient's torso, the hook fastener 11

contacts the loop fastener 7, with the hook fastener 11 on top. A plurality of straps 12 are used to secure the restraint to the dental chair. One pair of straps 12 is attached to the headpiece 3 and ties around the head of the dental chair by connecting the hook fastener 11 affixed to the top of one strap 12 with the loop fastener 7 affixed to the bottom of the other strap 12. Another pair of straps 14 (or alternatively two pair) is attached to the main body portion 1 and ties around the armrests of the dental chair (or the back of the chair if there are no armrests) by means of hook and loop fasteners arranged such that each strap 14 has a hook fastener 11 at its proximal end and a loop fastener 7 at its distal end.

The cushion 15 is preferably about four inches thick, is generally rectangular with an arcuate indentation 17 at the top end which holds the child's buttocks and counteracts the effect of gravity by preventing the child from sliding downward in the dental chair. The cushion 15 is encased in a similarly shaped pillowcase 21 which has a zipper 33 to allow the cushion 15 to be removed for washing and which has a non-slip rubber backing 2 to adhere to the vinyl of the dental chair. A pair of flaps 22, having a hook fastener 11 on one and a loop fastener 7 on the other, is attached to the pillowcase 21 and folds together to hold the child's legs in position. If the dental chair lacks armrests, straps can be attached to the pillowcase 21 to be tied around the chair. The cushion 15 can be adjusted to accommodate different size children by overlapping it on the main body position 1 of the restraint to the length desired.

As an optional feature, a pair of Velcro strips may be provided on each of the pieces (loop Velcro on the top surface of the lower part of the main body portion 1 of the restraint and hook Velcro on the rubber backing 2 of the pillowcase 21 covering the cushion 15) so as to enable the cushion to not only be overlapped onto the restraint, but also to be attached to the restraint, thereby preventing sliding to an even greater extent.

Another optional feature is that slide locks or buckle closures may be used instead of Velcro to fasten straps 12 to the chair or to fasten straps 14 to the chair.

We claim:

1. 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 patient's torso in position, a plurality of 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.

* * * * *



Dedicated to Healthy Teeth and Bright Smiles!

6-3-1997

Dear Sir or Madam,

Would you be so kind to expedite the process of this application so that many children will be able to benefit from this product. In addition it will help the government save millions of dollars before the summer ended (As it's by the school rules that children must have dental exam and treatment before entering school). Please see the attached press release sheet.

Yours sincerely.

A handwritten signature in black ink, appearing to read "Vachanee S. Peterson".

Vachanee S. Peterson D.D.S

Handwritten initials in the bottom right corner, possibly "VSP".

For immediate release

NEWS RELEASE: Minnesota Dentist Develops New Device to Assist in Children's Dentistry and Saves Her State 3 Million Dollars Over the Last Two Years

Summary: Saves Money, Reduces Use of Drugs, Makes Parent a Partner with Dentist

A Minnesota dentist has developed a securing device for the treatment of children which saves taxpayers millions of dollars, reduces the use of drugs in dentistry, and invites parents into the treatment process.

Dr. Vacharee Peterson, with the assistance of Catherine Boler, an adaptive clothing designer, has developed the *PedoCush*, a device which helps in the treatment of children by dentists without the use of expensive drugs.

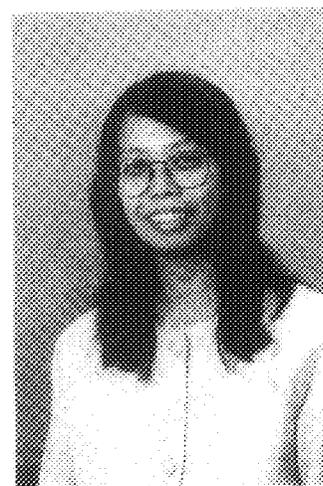
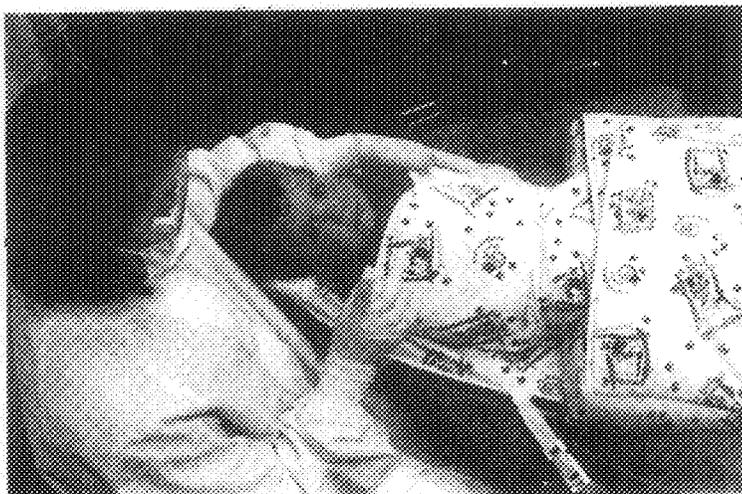
In the case of small children with severe decay, dentists and parents have several choices: ignore the problem until the child experiences pain, or use sedative drugs or general anesthesia which can have serious side effects. With general anesthesia, most dentists refuse to treat children in their office and send them to a hospital. In addition to dental fees, the cost for anesthesia is over three thousand dollars.

Over the past two years the dentists at the Peterson clinic have seen over 2,000 very young children with severe decay or behavior problems who are Medicaid recipients. By using the *PedoCush* instead of sending these children to the hospital, Dr. Peterson has saved Minnesota taxpayers an estimated \$3,000,000 over the last two years.

The *PedoCush* adapts an adult-sized dental chair into a child-friendly chair in seconds and stabilizes the child's body so he can't fall off. The parent remains at his side, gently holding him or massaging his hands and whispering soothing comments to him.

Dr. Peterson states: "We have simply taken an age-old concept reflected in the Indian use of the papoose board and adapted it to modern dental practice. The *PedoCush* not only helps with a natural approach to dentistry, but draws the parent in as a partner. The child is not snatched from the family atmosphere into an alien situation, but the dental experience is fused into the family context. Additionally it frees the child from drugs, and saves lots of money."

The *PedoCush* is marketed by *Cosily Free Kids*, 1224 Arcade St. St. Paul, MN, 55106. (612-774-0583)



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