APR 22 2003

K030283

510(k) Summary

Submitted by:

Company Name:	**Prism Enterprises LP**
Address:	6952 Fairgrounds Pkwy.
	San Antonio, TX 78238
Telephone:	1-800-648-9822
Fax:	210-520-7463

CONTACT PERSON: **Barb Wills**

DATE PREPARED: **01-22-03**

TRADE NAME: **Baby Pod**
COMMON NAME: pediatric carrier- stretcher accessory

SUBSTANTIALLY EQUIVALENT TO: The **Baby Pod** is substantially equivalent to WEEVAC 6 Infant Evacuation Stretcher (K902521). The TransWarmer® warmer mattress, an accessory used with the Baby Pod, was previously cleared for market (K934631.) The Baby Pod has the same intended use and similar indications for use as the predicate device. The minor technological differences (materials of construction and configuration) are more contemporary than those of the WEEVAC 6, but are well characterized and materials in contact with the baby are biocompatible.

DESCRIPTION of the DEVICE: **Baby Pod** is designed to convey a baby to or from a medical facility, between facilities or between departments within a single medical facility. **Baby Pod** consists of a lightweight carbon fiber outer shell, which is lined with a shock absorbent foam inner layer, and has transparent shields for viewing the baby. **Baby Pod** contains a patient positioning vacuum mattress, stretcher fixing straps to secure the device for transport, and safety straps to secure the baby inside the device during transport.

INDICATIONS FOR USE:
Baby Pod is intended to convey a baby to or from a medical facility, between facilities or between departments within a single medical facility.

SUMMARY of TESTING:
Material components in contact with the baby have been evaluated in accordance with ISO-10993 recognized test methods and found to be biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2003

Prism Enterprise, Incorporated
C/O Ms. Elaine Duncan
Paladin Medical, Incorporated
P.O. Box 560
Stillwater, Minnesota 55082-0560

Re: K030283
Trade/Device Name: Baby Pod
Regulation Number: 880.6900
Regulation Name: Hand-carried Stretcher
Regulatory Class: I
Product Code: FPP
Dated: January 22, 2003
Received: January 27, 2003

Dear Ms. Duncan:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K030283

Device Name: _____

Indications for Use:

Baby Pod is intended to convey a baby to or from a medical facility, between facilities or between departments within a single medical facility.

(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)

Patricia Cucente

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

510(k) Number: K030283