K981860

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PARAWORKS ENTERPRISE LTD.
#1-179 West 17th Avenue, Vancouver, British Columbia, Canada, V5Y 1Z7

510(K) SUMMARY

Feb 28, 1999

510(k) Number: K981860
Proprietary Name: AP Harness
Common Name: Safety Harness for Medical lines
Classification Name: Set, tubing and Support
Classification Number: BZO
Regulatory Class: II
Contact person: Michael Campbell, president, **PARAWORKS ENTERPRISE LTD.**
Substantially Equivalent to: Baxter's SiteLock™ Epidural Catheter Securement Device

Description:

The A.P. Harness System facilitates increased safety and comfort of the active child or other patient while he/she is hooked-up to TPN, IV, enteral tube feed or other medical lines. This safety is accomplished by providing the maximum distance between the child and pump stand, determined by the length in the medical lines. This allows the child better access to his/her environment. The harness also limits kinking and subsequent occlusion in the medical lines. This frees the child from interruptions in play, while the caregiver searches for the location of an occlusion in the medical lines. Another benefit is increased safety and lowered stress for the caregiver. This means the supervision of the medical lines is done less intensively, and therefore the caregiver's attention can be directed to the child as a whole person and not just as a patient.

This system is comprised of a harness, a tether strap, an anchor strap, and a zipper sleeve. It is equipped with buckles that are small, low profile, strong, and secure. The shoulder straps are moveable along the chest strap; this facilitates infinite adjustability for a growing patient or for multiple patient use. The chest strap is worn directly underneath the axillas (armpits), which facilitates unhindered diaper changes and avoids soiling. The harness's location high on the chest puts the minimum amount of restriction on the respiratory system, as well as keeping access for common medical evaluations and nursing procedures. The chest strap is made of soft tubular webbing, which contours to the patients chest, preventing abrasion and pinching.

Intended Use of the Device:

The AP Harness is to be used as a safety line between a patient and a medical machine whom are connected by a medical line, (ie IV tubing, oxygen tubing, enteral tubing, etc.). This device would be used when the patient or caregiver cannot maintain an adequate level of safety for a important catheter or other medical line.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 1999

Mr. Michael C. Campbell
President
Paraworks Enterprise Limited
#1-179 West 17th Avenue
Vancouver, British Columbia
Canada, V5Y IZ7

Re: K981860
Trade Name: AP Harness
Regulatory Class: I
Product Code: KMK
Dated: February 28, 1999
Received: March 11, 1999

Dear Mr. Campbell:

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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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

Applicant: **PARAWORKS ENTERPRISE LTD.**
510(k) Number: K981860
Device Name: AP Harness

Indications For Use:

The AP Harness is to be used as a safety line between a patient and a medical machine which are connected by a medical line, (ie IV tubing, oxygen tubing, enteral tubing, etc.). This device would be used when the patient or caregiver cannot maintain an adequate level of safety for an important catheter or other medical line.

(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 ✓

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981860

(Optional Format 1-2-96)