



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 26 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Duane R. Elliott
Emergent Innovations, Ltd.
P.O. Box 40773
Indianapolis, Indiana 46240

Re: K982178
Trade Name: Vagabond Soft Restraint System
Regulatory Class: I
Product Code: FMQ
Dated: October 27, 1998
Received: October 29, 1998

Dear Mr. Elliott:

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 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). 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 requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

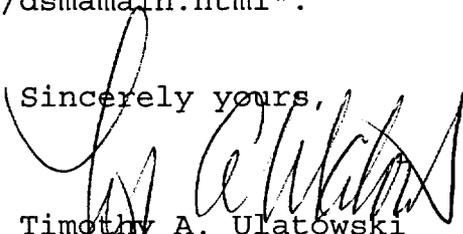
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (21CFR 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/dsma/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

Indications For Use

510(k) Number (if known) K-982178

Device Name: Vagabond Soft Restraint System

Indications For Use:

Vagabond for Neonatal Transport: This soft restraint system is indicated for transport of neonates from one hospital to another when isolets are necessary for perservation of life. The Vagabond Neonate Transport System safely insures the well being in the event of sudden jarring or accident. The neonate is proteced withi this special device from lateral or vertical movement due to collision or rough ride.

Vagabond for EMS Transport: This application is used for adults and pediatic patients when they are picked up in the field by Emergency Medical Service personnel and an EMS board is used for transport. Instead of using single straps the Vagabond provides eight points of secure side release locks along iwth a combination of webbing and netting to safely secure the patient to the baord for transport.

Vagabond for Papoose Application: The papoose application is necessary for the pediatic patients who require emergency room procedures sucha as suturing or other Minor procedures where they need to remain tionary. The Vagabond board and restrain system comfortably holds the child in place and can serve as an aid for transport whent he child might need to be transferred to another dept. of a hospital. This is accomplished by merely lifting the patient and the board onto a cot or rolling bed.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Device Evaluation, Control,
and General Hospital Equipment
510(k) Number K982178

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Indications For Use

510(k) Number (if known) K-982178

Device Name: Vagabond Soft Restraint System

Indications For Use:

Vagabond for bed restraint: This restraint is used when patients are sedated or disoriented and there is concern over thier falling out of bed. The Vagabond restraint helps to insure the safety of the patient by providing a comfortable restraint that serves to keep them in bed.

(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)

○

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