K974296

JA - 6 1998

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510(k) SUMMARY

Invacare Corporation's
Model 720 Series Full/Semi Electric and 1120 Full Electric Beds

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person: Edward A. Kroll
Director, TQM and Regulatory Affairs

Date Prepared: August 1, 1997

Name of Device and Name/Address of Sponsor

Model 720 Series Full/Semi Electric Bed and 1120 Full Electric Bed

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name

Nursing Home Bed

Classification Name

AC Powered Adjustable Hospital Bed

Predicate Devices

The Model 720 Series Full/Semi Electric Bed and 1120 Full Electric Bed are substantially equivalent to Invacare Corporation's 5110, 5210, 5310 and 5410 Series of Home Care Beds (K925534).

Intended Use

The intended use of the Model 720 Series Full/Semi Electric and 1120 Full Electric Beds is to provide added comfort during periods of bedrest by permitting the user to adjust the surface contour of the bed to various positions.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Model 720 Series Full/Semi Electric and 1120 Full Electric Beds are a series of nursing home beds with an intended function of providing added comfort during periods of bedrest. Additionally they permit the user to adjust the surface contour of the bed to various positions which best suit the specific needs of the bed user.

The 720 and 1120 product lines include a steel frame construction with motorized adjustments which are controlled through a pendant. The pendant controls are completely sealed and are available in four or six button configurations. Each series has variety of options and accessories which vary according to model number. Some options include floor locks, lock-out switches and perforated pans. Accessories include various side rails, IV sockets, IV rods and trapeze.

B. Substantial Equivalence

Products which are substantially equivalent to the 720 Series and 1120 Electric Beds are; Invacare's Model 5110, 5210, 5310 and 5410 Series Home Care Beds (K925534).

Each of these products have motorized head and knee section adjustments, a pendant type push button controller and an optional motorized or manual bed height adjustment. Additional similarities are a screw type linear actuator for positioning adjustment and locking casters for maneuverability. Additionally, all provide a means for selecting and adjusting the type of surface contour and positioning which best suits the needs of the bed user. Finally, all of these devices have been granted marketing clearance by FDA under prior submissions.

None of the differences between the Model 720 Series and 1120 Electric Beds and their predicate devices alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness.

Performance Data

The 720 Series and 1120 Electric Beds have all been tested for and meet the requirements listed with Underwriters Laboratories (U.L.) under the 544 Standard for Safety, for Medical and Dental Equipment. They include a low voltage control system and thermal protection on the motors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 1998

Mr. Edward A. Kroll
Director, TQM and Regulatory Affairs
Invacare Corporation
899 Cleveland Street
Elyria, Ohio 440362-2125

Re: K974296
Trade Name: Model 720 Series Full/Semi Electric Bed 1120 Full Electric Beds
Regulatory Class: II
Product Code: FNL
Dated: November 3, 1997
Received: November 17, 1997

Dear Mr. Kroll:

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

K974296

510(K) Number (if known): *Unknown*

Device Name: *Model 720 Series Full/Semi Electric and 1120 Full Electric Beds*

Indications for Use:

To provide added comfort during periods of bedrest by permitting the user to adjust the surface contour of the bed to various positions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Rebecca Cucente
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974296

Prescription Use _____ OR Over-The Counter-Use ✓

(Optional Format 1-2-96)