Fresenius Medical Care

K091727

Fresenius Medical Care South Asia Pacific Pty Ltd

JUL - 6 2009

Fresenius Medical Care
South Asia Pacific Pty Ltd
ACN 128 754 218
Level 17, 61 Lavender Street
Milsons Point, NSW 2061
Australia
Tel: +61 (02) 9466 8000
Fax: +61 (02) 9929 5595

510(k) Summary

Submitter Information:

Fresenius Medical Care South Asia Pacific Pty Ltd
Artistic Healthcare Seating Division Pty Ltd
Level 17, 61 Lavender Street
Milsons Point NSW 2061
AUSTRALIA

Contact Person:

Mr Ram Kamath
Quality, Regulatory Affairs & Management Systems Manager - South Asia Pacific
Fresenius Medical Care South Asia Pacific Pty Ltd
T: +61 2 9466-8023
F: +61 2 9466-8073
e: sr.kamath@fmc-asia.com

Manufacturer:

Artistic Healthcare Seating Pty Ltd, (Subsidiary of Fresenius Medical Care South Asia Pacific Pty Ltd)
13-15 Century Drive
Braeside VIC 3195
Australia

Device Information:

Trade/Proprietary Name:	Fresenius Medical Treatment Chair T-series
Common/Usual Name:	Medical Treatment Chair
Classification Name:	Chair, Electric, Positioning Chair, Dialysis, Powered Without Scales

Legally Marketed Predicate Device:

Convertible© I-Series Positioning and Transfer Chair

Device Description:

The range of chairs, used to aid medical procedures such as renal dialysis, blood collection and chemotherapy, are called Medical Treatment Chairs and are made up of models T-100, 200, 300, 400, 550, 500B, 550, 600, 600B, 650:

The *manually-operated* range of treatment chairs (T100, 200, 300) typically have the following features:

- Manually-operated recliner
- Adjustable head/neck rest
- Upholstered arms
- Four locking braked castors
- Vinyl-covered
- The T100, T200 and T300 models offer optional CPR support posts, gas spring assisted back rest and accessories, whilst other models come standard with these features
- Fold-down trays
- Fold-out arms

The *electric-powered* range of treatment chairs (T400 through to T600 series) offer the above features in addition to:

- power-operated seat and leg rest and back rest reclines, with some models offering one-touch memorized positions
- battery back-up – 24V rechargeable
- height-adjustable swing-out arm rests (except the T400)

The electric-powered chairs, depending on the model, may have different numbers of actuators, i.e:

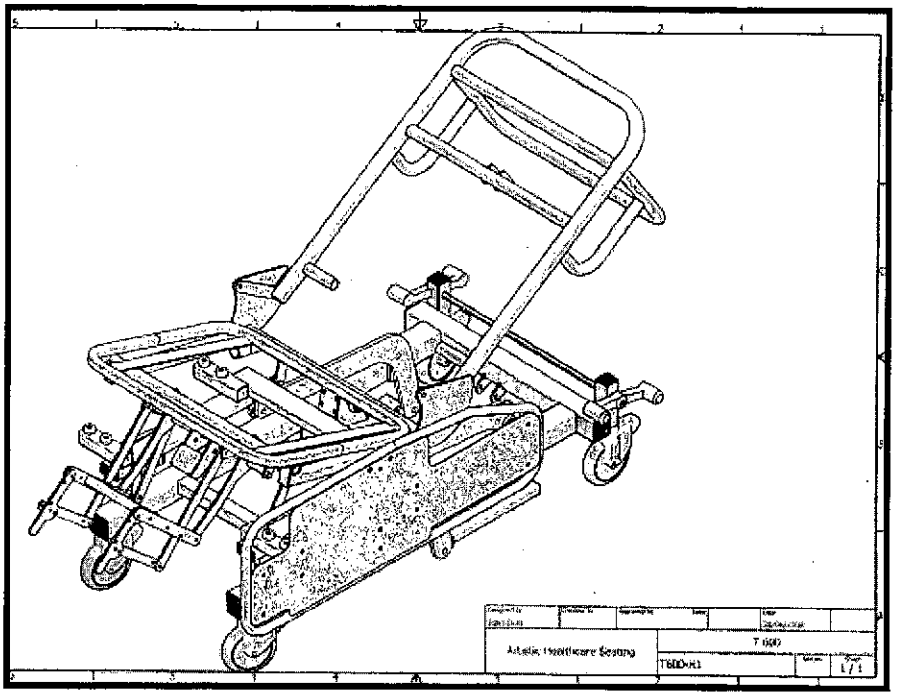
- T400 2 actuators
- T500 2 actuators
- T500B 2 actuators, reinforced frame
- T550 3 actuators
- T600 3 actuators
- T600B 3 actuators, 2 motors, reinforced frame, extra lift levers
- T650 3 actuators

The device is classified as:

- Class I (FMR)
- Class II (FKS, INO) – electric-powered version.

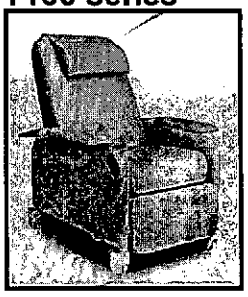
Specific ancillary devices and accessories are not listed here due to the wide variety of procedures in which the chair is used.

The following engineering drawing shows the final assembly for the T600 frame:

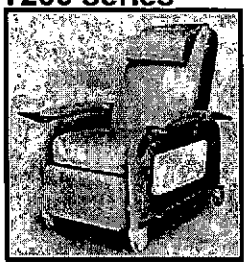


The configurations of the different models of chairs are shown in the photographs below:

T100 series

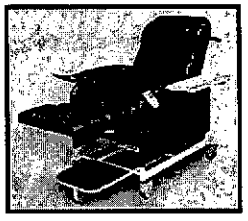


T200 series

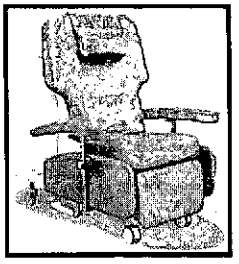


T300 series

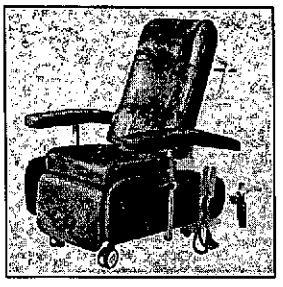
T400 series



T500 series



T600 series



MODEL	Length Upright (mm)	Length Tren/CPR (mm)	Overall Width (mm)	Seat Width (mm)	Weight Capacity (kgs)	Seat Height to Floor (mm)	Seat Height to Footstool (mm)	Backrest Length (mm)
T100 series	900	1800	860	550	130	470	n/a	700
T200 series	900	1800	860	550	130	470	n/a	700
T300 series	900	1800	860*	550	150	610	430	700
T400 series	900	1800	860*	550	150	610	430	700
T500 series	1030	1800	900	600	200	550	n/a	800
T550 series	1300	1800	900	600	200	550	n/a	800
T600 series	1300	1800	900	600	200	540-840	n/a	800

Intended Use:

The Medical Treatment Chairs are intended for use in medical procedures such as the administration of renal dialysis to, and taking bloods from, patients in hospital departments or home use, under the supervision of trained medical staff. The Medical Treatment Chairs are also intended for use in day surgery and nursing homes. The chairs are designed so that the occupant is accommodated in a seated position with the hips moved back so that the occupant's back is against the back rest and the legs outstretched and supported by the seat and leg rests.

The chairs are also used to position patients for easy access by healthcare professionals. The chairs are designed so that the occupant is accommodated in a seated position with the hips moved back so that the occupant's back is against the back rest and the legs outstretched and supported by the seat and leg rests.

All models are intended to be used by patients with a weight not exceeding:

- 130kg (T100 and T200 series)
- 130kg (T300 and T400 series)

- 200kg (T500, T550, T600 and T650 series)
- 300kg (T500B, T600B)

Substantial Equivalence:

The Fresenius Medical Treatment Chair T-600 and the predicate devices have similar, and in many cases the same:

- Intended Use
- Basic construction
- Principles of operation
- Electrical and mechanical characteristics
- General safety and EMC compliance

Performance Standards:

Although no performance standards or special controls have been developed under Section 514 of the FDC Act for Medical Treatment Chairs, Fresenius Medical Care South Asia Pacific Pty Ltd (Artistic Seating Healthcare Division) has chosen to test the Fresenius Medical Treatment Chair T-600 against self imposed load and repeatability test requirements. Representative samples for the device underwent load and repeatability testing to verify functional and performance characteristics.

Biocompatibility:

Materials used on the Fresenius Medical Treatment Chair T-600 that may come into contact with patients are biocompatible. The material was evaluated in accordance with guidelines of ISO 10993: Biological Evaluation of Medical Devices, Part 1: Evaluation and testing within a risk management process. The model chosen for testing was representative of other chairs in the series.

Electromagnetic Compatibility and Electrical Safety:

The Fresenius Medical Treatment Chair T-600 meets the applicable requirements of IEC 60601-1 General Safety and IEC 60601-1-2 EMC.

Cited Standards:

CRITICAL AREA	STANDARD
Quality System standards	ISO 13485:2003 (Medical devices -- Quality management systems -- Requirements for regulatory purposes)
Risk Analysis standards	ISO 14971:2000 (Medical devices -- Application of risk management to medical devices)
Design Control	
Flame retardant	California 117 sD p2 (Requirements, Test Procedure and Apparatus for Testing the Flame Retardance of Resilient Filling Materials Used in Upholstered Furniture) AS/NZS4088.1:1996 (Specification for burning behaviour of upholstered furniture - Upholstery materials for domestic furniture - Smouldering ignitability) AS 1530.3-1989 (Methods for fire tests on building materials, components and structures - Simultaneous determination of ignitability, flame propagation, heat release and smoke release)
Frame loading	AS 4688.2:2000 (Furniture – Fixed height chairs. Part 3: Determination of stability – Upright chairs, s8, s7.1)
Electrical	Whole Chair: • IEC60601-1. Linak actuators: • EN 60601-1-2:2002 EMC test specification for CB open Bus system • EMC parts of EN 1970:200, EN 60601-2-38:1997 and EN 60601-2-52:2007 • IEC 60601-1:1988+A1:91+A2:95 Dewert actuators: • EN 60601-1/A2:1995 • EN 60601-2-38:1996 • EN 60335-1/A2:2006 • EN 60601-1-2:2001 • EN 1970:2000 • EN 60529/A2:2000
Biocompatibility	ISO 10993-1:2003 (Evaluation and testing)
Castors and brakes	EN 12526 - 12533 Castors and wheels. Hospital bed castors.

Labelling	BS EN 1041:2008 Information supplied by the manufacturer of medical devices BS EN 980:2003 Graphical symbols for use in the labelling of medical devices
Clinical	AS ISO 14155-1: 2004 Clinical investigation of medical devices for human subjects - General requirements AS ISO 14155-2: 2004 Clinical investigation of medical devices for human subjects - Clinical investigation plans

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fresenius Medical Care South Asia Pacific Pty Ltd.
% Mr. Ram Kamath
Quality, Regulatory Affairs & Management
Systems Manager – South Asia Pacific
Level 17, 61 Lavender Street
Milsons Point, NSW
Australia 2061

JUL - 6 2009

Re: K091727
Trade/Device Name: Medical Treatment Chairs
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric positioning chair
Regulatory Class: II
Product Code: INO
Dated: May 8, 2009
Received: June 11, 2009

Dear Mr. Kamath:

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091727

Device name: Medical Treatment Chairs

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091727

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