



Food and Drug Administration
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September 17, 2014

Convaid Products, Inc.
Donald Griggs
Quality Assurance Manager
2830 California Street
Torrance, CA 90503

Re: K140416

Trade/Device Name: Trekker TR12 and TR14, Trekker Transit TR12T and TR14T
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR, LBE
Dated: August 8, 2014
Received: August 15, 2014

Dear Mr. Griggs:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); 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 Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K140416

Device Name
Trekker TR12 and TR14; Trekker Transit TR12T and TR14T

Indications for Use (Describe)

The Convoid Trekker models are manual wheelchairs; Their intended use is to provide mobility to persons with disabilities who are partially or permanently non-ambulatory and limited to a sitting position.
In addition the Trekker models TR12T and TR14T comply with the requirements of RESNA WC4:2012-section 19 Wheelchairs used as seats in motor vehicles.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Felipe Aguel -S Date: 2014.09.17
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Convaid Product Inc.
Model: Trekker Manual Wheelchairs
510(k) Summary
Of
Safety and Efficacy
Revised 8/27/2014

A. General Information

1. Submitter Name: Convaid Products Inc.
2. Address: 2830 California St.
Torrance CA, 90503
3. Telephone: 310-618-0111
Fax: 310-618-2172
4. Contact Person: Donald Griggs
Quality Assurance Manager
5. Registration Number: 2022883
6. Date Prepared: 03/27/2014

B. Device

1. Device Trade Name: Trekker TR12, TR14 &
Trekker Transit TR12T, TR14T
2. Common/Generic Name: Wheelchair-Manual
3. Device Classification Name: Mechanical Wheelchair
4. Registration Number: 2022883
5. Product Code: IOR
6. Device Classification: Class 1
7. Regulatory Number: 890.3850

C. Identification of Legally Marketed Devices

1. Manufacture Name: Convaid products Inc.
2. Name: Champ
3. K Number: K120501
4. Date Cleared: 10/20/2012

D. Description of the device

The Trekker TR12, TR12T and TR14, TR14T are attendant propelled manual wheelchairs. They are lightweight compact folding wheelchairs with tubular 6061 aluminum frames with removable seating modules for easy transport and stowage. The seating module is also reversible to allow the caregiver the option to observe the user during use.

Front small casters for steering and maneuverability and larger wheels in the rear. A tilt function for pressure relief and the recline function provide adjustability for the lower extremities.

Foot operated wheel locks provide easy operation.

Positioning options include H-harness, two point seat belt, three point seat belt with crotch pad additional non-positioning accessories include under seat storage basket, adjustable I.V. Pole.

Trekker transit option TR12T and TR14T transit models are identical to the TR12 and TR14 except for the factory installation of four (4) tie-down anchors and required labeling. They meet the requirements for use as seating in motor vehicles when used in conjunction with the vehicle supplied four (4) wheelchair tie-down system that attaches to the four (4) transport anchors on the wheelchair and a three (3) point occupant restraint system in accordance with SAE J2249 or WC4:2012 section 18 that creates the shoulder and lap belt combination that attaches to the wheelchair or to the floor of the vehicle.

E. Intended Use

The Convaid Trekker models are manual wheelchairs; their intended use is to provide mobility to persons with disabilities who are partially or permanently non-ambulatory and limited to a sitting position.

In addition the Trekker Transit models TR12T and TR14T comply with the requirements of RESNA WC4:2012-section 19 Wheelchairs used as seats in motor vehicles.

F. Technological Characteristics Summary

The Convaid Trekker is a standard manual folding aluminum frame wheelchair. The frame is made to be durable, lightweight and compact folding. The Trekker is an attendant propelled device with a removable seating module for easy stowage and transport. The seating module can be used facing in either direction this poses no additional risk as supported by the stability testing performed. Single piece height adjustable push handle for attendant comfort. Tilt and recline functions for pressure relief and comfort.

The transit models can be used as seating in a motor vehicle per RESNA WC4:2012 section 19.

G: Comparison of device characteristics to predicate

The Trekker models have similar characteristics (see comparison chart pages 4 and 5 this section), technology and are constructed of identical materials as the Convaid Champ models.

The Trekker and the Champ have lightweight tubular powder coated 6061 aluminum frames. They are designed to be compact folding for easy stowage and transport. The Trekker and the Champ models have removable seating modules in addition the Trekker's seating module can be used facing in either direction and the Champ models do not have this ability. The reversible seat module poses no new safety issues. The Trekker models fold using pivoting push handles tubes and side brackets and the Champ models uses a center cross brace to allow it to fold. These are both common designs in use today on folding non-rigid wheelchairs and the difference poses no additional risk. Both the Trekker and the Champ have tilt and recline functions, both have similar elevating height adjustable foot supports, headrest and push handle (optional on the Champ). Both having the same positioning options available H-harness, two or three point lap belts, foot positioners and depth adjustable crotch pad. The Trekker has two additional options available an I.V. Pole and an under seat storage basket, these options pose no additional risks.

The Champ models have a ten (10) inch seat width and the Trekker models have a twelve (12) and fourteen (14) inch seat widths. The different sizes are designed to accommodate different ranges of users and pose no additional risks as indicated by testing to RESNA wheelchair standards.

The Champ models have the availability of self or attendant propulsion with the optional push handle where as the Trekker models are only attendant propelled. This single function poses no additional risk to the device. They both have small casters in the front for steering and maneuverability and larger wheels in the back. The attendant propelled operating characteristics and maneuverability is equivalent and is recommended for indoor or outdoor use on flat firm terrain.

The optional transit models designated with a "T" after the model number can be used as seating in a motor vehicle per ANSI-RESNA WC Vol-1-section 19:2000 Champ or WC4:2012 section 19 for the Trekker. Both the Trekker optional transit models TR12T, TR14T and the Champ CH10T optional transit model have the addition of four (4) tie-down anchors factory installed to the standard units, no other structural modification are performed. They were tested with an approved four (4) wheelchair tie-down system and a three (3) point occupant restraint system in accordance with SAE J2249 or WC4:2012 section 18.

Both the Trekker and the Champ have the same intended use to provide mobility to persons with physical disabilities who are partially or permanently non-ambulatory and limited to a sitting position and as use as seating in motor vehicles.

Trekker Comparison table to the Champ

	TR12	TR12T	TR14	TR14T	CH10	CH10T	Comparison to Predicate
Seat width	12 “	12 “	14”	14”	10”	10”	Similar no impact on safety and effectiveness
Seat depth	6” to 12”	6” to 12”	9” to 16”	9” to 16”	8” to 10”	8” to 10”	Same as above
Seat to back height	15” to 21”	15” to 21”	17” to 26”	17” to 26”	11 & 15”	11 & 15”	Additional height poses no additional risk
Seat to footrest	6” to 14”	6” to 14”	6” to 14”	6” to 14”	7.5” to 12”	7.5” to 12”	Similar in range no impact on safety and effectiveness
Footplate 1 piece adjustable	+/- 15°	+/- 15°	+/- 15°	+/- 15°	-20° +10°	-20° +10°	Same as above
Seat to floor	16” – 25”	16” – 25”	17” – 25”	17” – 25”	15”	15”	Relative to users size, testing show no effect on safety or efficacy
Recline/Seat to back angle	80° to 100°	80° to 100°	80° to 100°	80° to 100°	80° to 120°	80° to 120°	testing shows no effect on safety or effectiveness
Optional recline/ seat to back angle	80° to 170°	80° to 170°	80° to 170°	80° to 170°	N/A	N/A	RESNA WC1-1 Static stability testing shows no effect on safety or effectiveness * Testing was performed in a stationary position
Tilt adjustment	-5° to 45°	-5° to 45°	-5° to 45°	-5° to 45°	0° to 45°	0° to 45°	Similar no impact on safety and effectiveness
Headrest Support	6”	6”	6”	6”	4” to 8”	4” to 8”	Same as above
Chair weight	32 lbs	32 lbs	33 lbs	33 lbs	26 lbs	26 lbs	Weight range is size dependant test results are satisfactory
Chair width	24.3”	24.3”	26.3”	26.3”	22”	22”	Similar no impact on safety and effectiveness
Overall height	37.5”	37.5”	37.5”	37.5”	38”	38”	Similar no impact on safety and effectiveness
Overall length	42”	42”	42”	42”	26”	26”	Trekkers larger length would enhance stability
Weight capacity	75 lbs Std or transit	75 lbs Std or transit	110 lbs Std or transit	110 lbs Std or transit	66 lbs. Std or transit	66 lbs. Std or transit	Relative to users size, testing show no effect on safety or effectiveness
Tilt in space	Single mech. lock	Single mech. lock	Single mech. lock	Single mech. lock	Single mech. lock	Single mech. lock	Same functionality

Comparison Table Continued

	TR12	TR12T	TR14	TR14T	CH10	CH10T	Comparison to Predicate
Removable seating module with seat and back cushions	Yes	Yes	Yes	Yes	Yes	Yes	All have removable seating modules
Transit Option	No	Yes	No	Yes	No	Yes	Tested to WC section 19 requirements
Frame tubular 6061 Aluminum	Yes	Yes	Yes	Yes	Yes	Yes	Same materials
Upholstery and fabric accessories	Same	Same	Same	Same	Same	Same	Identical fabrics on all models
Wheel locks	Foot actuated	Foot actuated	Foot actuated	Foot actuated	Hand toggle	Hand toggle	Tested and results show no impact on safety and effectiveness
Footplate	One piece	One piece	One piece	One piece	One piece	One piece	Similar no impact on safety and effectiveness
Frame coating	Powder coated	Powder coated	Powder coated	Powder coated	Powder coated	Powder coated	Identical coating used on all models
Camber	N/A	N/A	N/A	N/A	8° non-Adjustable	8° non-Adjustable	Camber is only on self propelled devices no impact on safety and effectiveness
Front caster diameter	7.5"	7.5"	7.5"	7.5"	4"	4"	Different size tires pose no additional risks
Rear wheel diameter	11.4"	11.4"	11.4"	11.4"	20"	20"	Different size tires pose no additional risks
Patient contacting surfaces Upholstered items seat, backrest, H-harness strap covers, foot positioners and headrest cover	Cordura, Spacer fabrics & ballistic nylon	Same	Same	Same	Same	Same	Identical materials as used on predicate
Patient contacting surfaces Frame 6061 powder coated aluminum	Same	Same	Same	Same	Same	Same	Identical materials as used on predicate
Attendant or self propelled	Attendant	Attendant	Attendant	Attendant	Self or Attendant	Self or Attendant	When compared as attendant propelled same functionality



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H: Non-Clinical Testing

Convaid's Trekker manual wheelchairs meet the applicable performance requirements as specified below;

ANSI-RESNA WC 1:2009-1
ANSI-RESNA WC 1:2009-5
ANSI-RESNA WC 1:2009-7
ANSI-RESNA WC 1:2009-8
ANSI-RESNA WC 1:2009-11
ANSI-RESNA WC 1:2009-13
ANSI-RESNA WC 1:2009-15
ANSI-RESNA WC 1:2009-16
ANSI-RESNA WC 1:2009-22
ANSI-RESNA WC 1:2009-26
ANSI-RESNA WC 2:2009-3
RESNA WC4:2012 section 19 (Trekker) WC Vol.1 section 19:2000 (Champ)
ISO 10993-5

I: Storage / Shelf life:

The Trekker model wheelchairs are built to order so storage/shelf life concerns would only occur after delivery to the purchaser.

Storage procedures are covered in the user's guide "Unit should be stored in a clean, dry area and avoid extended exposure to moisture. After extended storage periods and before use the entire chair needs to be serviced". Owner should reference user's guide maintenance section and chart for periodic maintenance and inspections.

J: Biocompatibility:

Type of contact: Skin Contact duration category C >30 days.

Patient: Contact of intact skin of hands and arms with the following materials.
Cordura fabric, spacer fabric, transient contact with intact skin of the hands, neck and feet with ballistic nylon and aluminum frame.

Conclusion: Trekkers use the identical patient contacting materials used in the predicate devices Convaid Champs and does not raise any new biocompatibility issues.

K: Safety and Effectiveness:

The Trekker series and the Champ series share technology, design, performance and construction materials and does not raise any new issues of safety and effectiveness.



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L: Conclusion:

The Trekker TR12, TR14 and Trekker transit TR12T and TR14T wheelchair series shares performance, design technology and intended use with the predicate devices Convaid Champ CH10 and Champ transit CH10T cleared on 10/20/12 on K120501. There are no significant differences between the Trekker and Trekker transit wheelchairs and the Champ and Champ transit wheelchair that would raise any new issues of safety and effectiveness therefore the Trekker and Trekker transit wheelchair series are substantially equivalent to the predicate devices.