



October 18, 2017

Convoid Products Inc.
% Donald Griggs
Quality Assurance Manager
Convoid Products llc.
2830 California St
Torrance, California 90503

Re: K171017

Trade/Device Name: Convoid Flyer FL12, FL13, FL14, FL15 and FL16
Convoid Flyer transit FL12T, FL13T, FL14T, FL15T and FL16T
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR, LBE
Dated: August 22, 2017
Received: September 19, 2017

Dear Donald 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 (DICE) 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" (21 CFR 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 (DICE) 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
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)

K171017

Device Name

Convaid Products Flyer Series Manual Wheelchairs

Convaid Flyer FL12, FL13, FL14, FL15 and FL16

Convaid Flyer transit FL12T, FL13T, FL14T, FL15T and FL16T

Indications for Use (Describe)

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

In addition the Flyer Transit models FL12T, FL13T, FL14T, FL15T and FL16T comply with the requirements of RESNA WC4:2012 section 19 Wheelchairs used as seating 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



2830 California Street Torrance, CA 90503
 888-CONVAID 310/ 618-0111
 www.convaid.com

**Convaid Product Inc.
 Model: FLYER Manual Wheelchair
 K171017
 510(k) Summary of
 Safety and Efficacy
 Revised 10/17/2017**

A. General Information

Submitter Name	Convaid Products LLC.
Address	2830 California Street Torrance, CA 90503
Phone	(310) 618-0111
Fax	(310) 618-2172
Contact Person	Don Griggs, Quality Assurance Manager
Registration Number	2022883
Date Prepared	08/28/2017

B. Device

Device Trade Name	Flyer	FL12, FL13, FL14, FL15, FL16
	Flyer Transit	FL12T, FL13T, FL14T, FL15T, FL16T
Common/Generic Name	Wheelchair-Manual	
Registration Number	2022883	
Product Code	IOR, LBE	
Device Classification	Class 1	
Regulatory Number	890.3850	

C. Identification of Legally Marketed Devices

Manufacture Name	Convaid Products LLC.
Product Name	Convaid Trekker
510K Number	K140416
Date Cleared	09/17/2014

D. Indication of use

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

In addition the Flyer Transit models FL12T, FL13T, FL14T, FL15T and FL16T comply with the requirements of RESNA WC4:2012 section 19 Wheelchairs used as seating in motor vehicles.

E. Intended Use

Convaid's Flyer series are a lightweight ridge high strength aluminum and steel wheelchair base with a removable mobility seating system for everyday indoor and outdoor use on flat firm terrain. These persons typically have some form of neuromuscular disorder that limits their ability to self-propel such as Cerebral Palsy.

The end user of the Flyer models as with all Convaid attendant propelled wheelchair products is not determined by age but by body dimensions and mass, as such it is foreseeable that a person could include children and adults of all ages that may have a Convaid Flyer wheelchair recommended by a healthcare professional.

A risk analysis is performed on all Convaid products to evaluate the device including the possibility of children and or other impaired population groups to mitigate any safety issues as much as possible through design and labeling. Warnings and cautions are placed throughout the user's guide to alert caregivers.

F. Device Description

The Flyer series are attendant propelled manual wheelchairs constructed of the same materials and contain the same typical components and accessories found on most manual attendant propelled wheelchairs. The product consists of high strength powder coated tubular aluminum and steel plates that are welded, brazed, riveted or bolted. It comes standard with 5.5" front wheels attached to pivoting casters for steering and turning and 11.5" wheels in the rear. The product has a lightweight rigid base with a folding removable seating module, which is designed for everyday indoor or outdoor use on flat firm terrain. The Flyer offers its users a -5° to 40° range of continuously adjustable tilt-in-space achieved through the use of a single mechlok and hand lever to control the tilt action and 80° to 170° of seat to back adjustment (recline) that is controlled with a hand activated two plunger type pin system and plates on each side of the seating module with 10° incrementally located holes, the plungers pins engage to maintain the desired degree of recline. The chair comes standard with seat and back cushions that meet the requirements of WC1 section 16 for flammability and ISO 10993 biological evaluation of medical devices. However, the user also has the option of using a commercially available compatible seat and back cushion. The seat depth is set at the factory to one of four (4) depths and an adjustable back height of 17 to 23 inches.

Positioning accessories include a two point belt or three point belt with crotch pad, foot positioners, H-harness with padded covers, adjustable footplate, head support and adjustable headwing, flip-up armrests and LTV bracket. The Flyer Transit models are WC4:2012 section 19 transit approved for use as a seating in motor vehicles.

G. Comparison of Device Characteristics to Predicate

The Convaid Flyer has similar characteristics, accessories and technology and is constructed using identical materials as the predicate device, the Convaid Trekker cleared on 09/17/2014 K140416 (see comparison table below). Both are attendant propelled manual wheelchairs with similar operating characteristics and maneuverability and are recommended for indoor or outdoor use on flat firm terrain.

The Convaid Flyer has a ridge base frame and a removable seating module while the Trekker has a non-ridge base frame and removable seating module. Both systems attach to their bases using the same locking mechanism and allow for easy storage and transport. The Trekker's seating module can be placed on the base facing in either forward or rear configurations while the Flyer is only forward facing. The weight capacity variance is due to the Flyer having a ridge base allowing for a maximum weight capacity of 170lbs and the Trekker using a non-ridge/folding frame with a maximum weight capacity of 110 lbs.

The Flyer is available with seat widths from 12 to 16 inches in 1 inch increments, while the Trekker is available in a 12" or 14" inch seat width. The Flyer also allows for the adjustment of the chair width when using an optional growth kit from 12 inches up to 16 inches maximum in 1 inch increments. The growth feature is an available feature on other manufactures wheelchairs to allow for the changes in user mass and dimensions and as such poses no new risks.

The Convaid Flyer and the Convaid Trekker were subjected to the same RESNA wheelchair tests: WC1 section 1 static stability, section 8 static, impact and fatigue strengths, and section 16 resistance to ignition and WC2 section 3 determination of effectiveness of brakes as well as non- pass/fail requirements of Sections 5, 7, 11, 13 as referenced below in section H. The use of approved standards allows for the comparison of products that by virtue of completing and passing the same test requirements establishes a basis of functional comparability of the these two products.

Flyer Design Comparison Table to the Predicate Convaid Trekker

	FL12 to FL16	FL12T to FL16T	TR12 TR12T	TR14 TR14T
Seat width	12" to 16"	12" to 16"	12 "	14"
Seat depth "dependent of seat depth position 1 to 4"	15.5" to 25.5"	15.5" to 25.5"	6" to 12"	9" to 16"
Growth option (Width)	Yes	Yes	No	No
Seat to back height	17" to 23"	17" to 23"	15" to 21"	17" to 26"
Seat to footrest	5.8" to 11"	5.8" to 11"	6" to 14"	6" to 14"
Footplate 1 piece adjustable	+/- 15°	+/- 15°	+/- 15°	+/- 15°
Footplate individual angle Adjustable	Unlimited angle adjustment	Unlimited angle adjustment	No	No
Seat to floor	15"	15"	16" – 25"	17" – 25"
Seat to back angle/recline	80° to 170°	80° to 170°	80° to 170°	80° to 170°
Tilt-in-space adjustment	-5° to 40°	-5° to 40°	-5° to 45°	-5° to 45°
Headrest extension	8"	8"	6"	6"
Chair weight	29.2 lbs.	29.2 lbs.	32 lbs.	33 lbs.
Chair width	21" to 25"	21" to 25"	24.3"	26.3"
Overall height	40"	40"	37.5"	37.5"
Overall length	25.75"	25.75"	42"	42"
Weight capacity	85lbs Position 1 or 170lbs for 2 thru 4	85lbs Position 1 or 170lbs for 2 thru 4	75 lbs. Std. or transit	110 lbs. Std. or transit
Tilt in space	Single mech. lock	Single mech. lock	Single mech. lock	Single mech. lock
Removable seating module with seat and back cushions	Yes	Yes	Yes	Yes

Flyer Design Comparison Table to the Predicate Convaid Trekker

	FL12 To FL16	FL12T To FL16T	TR 12 and TR14	TR12T and TR14T
Transit Option	No	Yes	No	Yes
Frame tubular 6061 Aluminum	Yes	Yes	Yes	Yes
Upholstery and fabric accessories	Same	Same	Same	Same
Armrest option Are optional on both. *Note item added to Trekker after release	Yes	Yes	*Yes	*Yes
Wheel locks	Foot actuated	Foot actuated	Foot actuated	Foot actuated
Frame coating	Powder coated	Powder coated	Powder coated	Powder coated
Camber	N/A	N/A	N/A	N/A
Front caster diameter	6" or 7.5"	6" or 7.5"	6" or 7.5"	6" or 7.5"
Rear wheel diameter	11.5" or 16"	11.5" or 16"	11.5"	11.5"
Patient contacting surfaces Skin Contact duration category A < 24 hours. Upholstered items: seat, backrest, H- harness strap covers, arrest cover, foot positioners and headrest cover	Same	Same	Same	Same
Patient contacting surfaces Skin Contact duration category A < 24 hours. Frame 6061 powder coated aluminum	Same	Same	Same	Same
Attendant or Self- propelled	Attendant	Attendant	Attendant	Attendant

	FL12 To FL16	FL12T To FL16T	TR 12 and TR14	TR12T and TR14T
Indication for use	<p>The Convaid Flyer models are manual wheelchairs; they are intended to provide mobility to persons with disabilities who are partially or permanently non-ambulatory and limited to a sitting position. In addition the flyer Transit models FL12T, FL13T, FL14T, FL15T, FL16T comply with the requirements of RESNA WC4:2012section19 wheelchairs used as seating in motor vehicles</p>		<p>The Convaid Trekker models are manual wheelchairs; there 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.</p>	
Intended Use	<p>Convaid’s Flyer series are a lightweight ridge high strength aluminum and steel wheelchair base with a removable mobility seating system for everyday indoor and outdoor use on flat firm terrain. These persons typically have some form of neuromuscular disorder that limits their ability to self-propel such as Cerebral Palsy.</p>		<p>Convaid Trekker series are a lightweight ridge high strength aluminum and steel wheelchair base with a removable mobility seating system for everyday indoor and outdoor use on flat firm terrain. The Trekker are manual wheelchairs that provide mobility to persons with physical disabilities who are partially or permanently non-ambulatory and limited to a sitting position</p>	

H. Non-Clinical Testing

- RESNA WC-1:2009 Section 1 - Determination of static stability
- RESNA WC-1:2009 Section 5 – Determination of dimensions, mass and maneuvering space
- RESNA WC-1:2009 Section 7 – Method of measurement of seating and wheel dimensions
- RESNA WC-1:2009 Section 8 – Requirements and test methods for static, impact and fatigue strengths
- RESNA WC-1:2009 Section 11 – Test dummies
- RESNA WC-1:2009 Section 13 – Determination of coefficient of friction of test surfaces
- RESNA WC-1:2009 Section 15 – Requirements for information disclosure, documentation and labeling
- RESNA WC-1:2009 Section 16 - Resistance to ignition of upholstered parts – Requirements and test methods
- RESNA WC-2:2009 Section 3 – Determination of effectiveness of brakes
- RESNA WC-4:2012 Section 19 - Wheelchairs used as seats in motor vehicles
- ISO 10993-5:2009 – Tests for in vitro cytotoxicity
- ISO 10993-10:2010 – Tests for irritation and skin sensitization

Because the requirements have been met for the above listed standards and the performance tests for the Flyer series and Trekker series yielded similar results we have determined that there are no new risks to the safety or effectiveness of the device and it is therefore substantially equivalent.

I. Storage / Shelf life

The Flyer model wheelchairs are built to order and storage/shelf life concern 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". The owner should reference user's guide maintenance section for periodic maintenance and inspections.

J. Biocompatibility

Type of contact: Skin Contact duration category A < 24 hours.

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

A biocompatibility assessment was carried out for patient contacting materials and conducted using a biomaterial evaluation with results indicating that it is compliant with ISO 10993-5. The Flyer uses the same patient contacting materials as the predicate device and does not raise any new biocompatibility issues.

K. Safety and Effectiveness

Both were subjected to the same ISO and RESNA wheelchair non-clinical performance testing and do not raise any new issues of safety and effectiveness.

L. Conclusion

The Flyer series share performance, design technology indications for use and intended use with the predicate devices, Convaid Trekker series cleared on 09/17/14 on K140416. There are no significant differences between the Flyer series wheelchairs and the Trekker series wheelchairs that would raise any new issues of safety and effectiveness based on the non-clinical performance tests and the analysis. Therefore the Convaid Flyer wheelchair series are substantially equivalent to the predicate devices.