



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

April 11, 2016

Winco Manufacturing LLC  
% Ronald M. Scott  
5516 SW 1st Lane  
Ocala, FL 34474

Re: K152056  
Trade/Device Name: Winco Model S550 Stretchair  
Regulation Number: 21 CFR 890.3690  
Regulation Name: Powered Wheeled Stretcher  
Regulatory Class: Class II  
Product Code: INK  
Dated: July 22, 2015  
Received: July 24, 2015

Dear Ronald M. Scott:

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" (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 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,

Carlos L. Peña 

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)

K152056

Device Name

Winco Model S550 Stretchchair

Indications for Use (Describe)

The intended use of the Winco Model S550 Stretchchair is to provide a method of transporting patients within healthcare facilities.

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.

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**Winco, LLC**  
**Model S550 Stretchchair**  
**510(k) Summary**  
(Modified April 8, 2016)

**I. SUBMITTER**

Winco Mfg., LLC  
5516 Southwest 1<sup>st</sup> Lane  
Ocala, Florida 34474  
Phone: (800) 237-3377  
Fax: (352) 854-9544

**II. DEVICE**

Name of Device: Winco Model S550 Stretchchair  
Common or Usual Name: Stretcher  
Classification Name: Powered, Wheeled Stretcher (890.3690)  
Regulatory Class: II  
Product Code: INK

**III. PREDICATE DEVICE**

Winco Stretchchair Model S999 (K110671)

**IV. DEVICE DESCRIPTION**

The Winco Model S550 Stretchchair is a battery powered device designed for use in healthcare facilities. Its' intended function and use is to transport patients within the confines of the healthcare facility, where patient care is being administered. It can also be used to support the patient during examinations and other clinical activity which may take place in the facility.

The Winco Model S550 Stretchchair has a powered height adjustment feature which allows patient surface to be raised and lowered for patient mounting and patient access. It also has a powered linear actuator which changes the patient surface from a sitting position to a laying (supine) position.

The patient can be transported only when in the seated position. (See Figures 1 and 2 below). When in the supine position, it can be used to transfer a patient to/from a bed, gurney or other patient support surface. The Winco Model S550 Stretchchair is for patients weighing up to 550 lbs. It is intended for indoor use only, by trained medical staff and health care personnel. There is no drive mechanism or power assist for moving the product from one physical location to another. This is performed manually by the medical staff. The device cannot be self-propelled by the patient.



Device Function:

The Winco Model S550 Stretchchair has three basic functions. These are; the patient transport function, the patient surface adjustment function and the height adjustment function. The patient transport function is dependent solely upon the healthcare facility attendant to transport the patient by physically pushing on the device push handles. The attendant controls the motion and direction of the device.

The patient surface adjustment function allows the patient to be seated or supine (laying down) while on the device. This function is achieved using a DC motor with worm gear type linear actuator. The adjustment from seated to supine is initiated by the attendant using a hand held controller. When engaged, the linear actuator pivots the patient surface either up or down to change the position from seated to supine or supine to seated. Limit switches disable power to the motor when travel limits are reached.

The height adjustment function raises or lowers the patient surface. This is achieved using a DC Powered hydraulic pump and four hydraulic cylinders. The lift mechanism is activated by the attendant using the same hand held pendant control. When raised, hydraulic fluid is simultaneously pumped into the four cylinders, which then extend and raise the chair frame upward. When lowered, the flow of hydraulic fluid is reversed and returns the cylinders to their compressed state.

Scientific Concepts

There are no complex scientific concepts related to the Winco Model S550 Stretchchair. The patient adjustment function uses a standard worm gear type linear actuator. The lift mechanism use standard hydraulic cylinders to achieve its function.

Significant Physical and Performance Characteristics:

Design:

- The patient can be transported in the sitting position only
- Powered Height Adjustment
- Powered sitting/supine adjustment
- Adjustable Armrests
- Adjustable Footrests
- Locking Casters
- Hand Held Pendant Control

Materials:

Materials used are:

- Steel frame and support members



- Plastic casters
- Vinyl covered upholstery

Physical Properties:

The Winco Model S550 Stretchchair consists primarily of the following;

1. Stretcher Base and Chair Frame :  
Made from steel and with a powder coated finish. Base is used to support the stretcher and lift mechanism. Chair is used structure and user support.
2. Hydraulic Lift System  
Used to raise and lower entire chair in either the sitting or supine position.
3. Casters  
Made from plastic and steel. Used for transport (steering, prevent movement, etc...)
4. Actuator System  
Transfers chair seat and back from upright sitting position to lay-flat position.

**V. INDICATIONS FOR USE**

The intended use of the Winco Model S550 Stretchchair is to provide a method of transporting patients within healthcare facilities.

**VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The technology and principle of operation for the Winco Model S550 Stretchchair and Winco Model S999 Stretchchair is identical. Both products are electromechanical devices with the intended function and use of providing a method of transporting patients within a health care facility. They have the same indications for use, have the same features and performance characteristics and are made from the same materials. They utilize the same technology and they all function in the same manner.

Both products include a frame assembly, a patient support surface, a power lift actuator for adjusting the height of the device and for adjusting the patient surface from a seated position to a supine position and both are battery powered. Additionally, both can be used to transport a patient in a seated position. They use the same identical lift mechanism, linear actuator, hand control pendent, upholstery, and casters.

Discussion of Similarities and Differences:

The primary difference between Winco Model S550 Stretchchair and Winco Model S999 Stretchchair is that the Winco Model S550 Stretchchair has a patient weight limitation of 550 pounds whereas the Winco Model S999 Stretchchair has a patient weight limitation of 1000 pounds. Also, the Winco Model S550 Stretchchair is 6" narrower than the Winco Model S999 Stretchchair. This narrower frame is designed to better accommodate the smaller, 550 pound patient.



This 6" narrower width does not affect safety, effectiveness or substantial equivalence. The smaller width is the result of the lower weight limitation. It allows for a better patient fit than the wider predicate and like the predicate, the Winco Model S550 Stretchchair is labeled with a maximum allowed patient weight. The difference only means that it is not to be used on a patient that exceeds 550 pounds.

This 6" narrower width does not affect safety, effectiveness or substantial equivalence. The smaller width is the result of the lower weight limitation. It allows for a better patient fit than the wider predicate and product is labeled with the maximum allowed patient weight.

Based on the above discussion, Winco Mfg., LLC believes that the Winco Model S550 Stretchchair is substantially equivalent to the Winco Model S999 Stretchchair (K110671). While there are some differences between the Winco Model S550 Stretchchair and its predicate, these differences are minor and do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness.

## VII. PERFORMANCE DATA

The Winco Model S550 Stretchchair meets the following standards.

- IEC 60601-1 Medical Electrical Equipment Part 1: General Requirement for Safety and;
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

The upholstery used on the Winco Model S550 Stretchchair is made from the same materials as the upholstery used on the Winco Model S999 Stretchchair (K110671).

## VIII. CONCLUSIONS:

Performance testing and use of the same identical lift mechanism and linear actuator supports the safety of the Winco Model S550 Stretchchair. Since the predicate was cleared in part on these data, conformance with the same requirements demonstrates that the Winco Model S550 Stretchchair will perform as intended in the specified use conditions. Further, technology, principle of operation and indications for use between Winco Model S550 Stretchchair and its predicate are identical. This demonstrates that it performs comparably to the predicate device that is currently marketed for the same intended use. Therefore, the Winco Model S550 Stretchchair is substantially equivalent to the Winco Model S999 Stretchchair.



FEATURE/SPECIFICATION	WINCO MODEL S550 STRETCHER	WINCO MODEL S999 STRETCHER	EXPLANATION OF DIFFERENCES.
510(k) Accession Number	K152056	K110671	NA
Clearance Date	TBD	April 22, 2011	NA
Intended Use	To provide a method of transporting patients within a health care facility	Same	No difference
Transport Method	Manual Only	Same	No difference
Transport Mode	Seated	Same	No difference
Maximum Patient Weight	550 lbs.	1000 lbs.	This does not affect safety, effectiveness or substantial equivalence. Like the predicate, the Winco Model S550 Stretcher is labeled with a maximum allowed patient weight. The difference only means that it is not to be used on a patient that exceeds 550 pounds.
Stretcher Length	72" (182.9 cm)	Same	No difference
Overall Width	34" (86.4 cm)	40" (101.6 cm)	This 6" narrower width does not affect safety, effectiveness or substantial equivalence. The smaller width is the result the lower weight limitation. It allows for a better patient fit than the wider predicate and product is labeled with the maximum allowed patient weight.
Overall Height	54" (137.2 cm)	Same	No difference
Seat Width	25" (63 cm)	31" (78.7 cm)	This 6" narrower width does not affect safety, effectiveness or substantial equivalence. The smaller width is the result the lower weight limitation. It allows for a better patient fit than the wider predicate and product is labeled with the maximum allowed patient weight.
Vertical Lift Range (Total Range)	22" (55.9 cm) – 38" (96.5 cm)	Same	No difference
Travel Speed Height	Low to High = 25 seconds High to Low = 28 seconds	Same	No difference
Supine Travel Speed	Upright to Supine = 25 seconds Supine to Upright = 26 seconds	Same	No difference
Height Adjustment Method	Hydraulics	Same	No difference. The Winco Model S550 Stretcher uses the same lift mechanism as its' predicate
Seat/Supine Drive Mechanism	Motor Driven Linear actuator	Same	No difference. The Winco Model S550 Stretcher uses the same motor driven linear actuator as its' predicate
Battery Powered	Yes	Yes	No difference
Trendelenburg Position	No	No	No difference