K061186

510(k) Summary of Safety and Effectiveness

MAY 12 2006

A. GENERAL INFORMATION

1. Submitter's Name:	Aero Innovative Research, Inc.
2. Address:	500 W. Clay Street Valley Center, KS 67147
3. Contact Person:	Matt Cochran
4. Date prepared:	March 6, 2006
5. Registration Number:	Applied For

B. DEVICE

1. Proprietary or Trade Name:	Flight
2. Common Name:	Mechanical Wheelchair
3. Classification Name:	Wheelchair, Mechanical
4. Classification Panel:	Physical Medicine
5. Product Code(s):	IOR
6. Class for New Device:	Class I
7. Regulation Number:	890.3850

C. INDICATIONS FOR USE

Model Flight Mechanical Wheelchairs are indicated for providing mobility to persons limited to a sitting position.

D. DESCRIPTION OF THE DEVICE

The AIR, Inc. Model "Flight" mechanical wheelchair is an indoor/outdoor wheelchair that has a base with two larger rear wheels and two smaller front wheels and a seat. The device can be easily folded for transport.

E. PERFORMANCE TESTING

The "Flight" mechanical wheelchair meets the applicable voluntary ANSI/RESNA standards for mechanical wheelchairs. The upholstery meets ANSI/RESNA WC Volume 1, Section 16: Determination of flammability.

F. LEGALLY MARKETED DEVICE FOR SUBSTANTIAL EQUIVALENCE COMPARISON

1. Manufacturer:	Otto Bock, LP
2. Model:	Start Basic
3. Cleared under:	K052681
4. Date Cleared:	October 6, 2005
5. Class:	Class I
6. Regulation Number	890.3850
7. Product Code(s):	IOR

G. SUMMARY OF SUBSTANTIAL EQUIVALENCE COMPARISON

The new device and the predicate device have the same intended use. Both devices have the same weight bearing capacity and both devices are foldable for transportation or stowage. The overall dimensions are similar. The differences between the new device and the predicate are chiefly in the frame materials and in overall dimensions. These differences are not safety related, so the new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2006

Aero Innovative Research,Inc
c/o Ms. Silvia Ankova
Underwriters Laboratories, Inc.
333 Pfingsten Rd.
Northbrook, Illinois 60062

Re: K061186
Trade/Device Name: Flight
Regulation Name: Mechanical Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: April 24, 2006
Received: April 28, 2006

Dear Ms. Ankova:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

510(k) No.
If known _____

Indications For Use statement

Device Name: Flight

Indications For Use:

Model Flight Mechanical Wheelchairs are indicated for providing mobility to persons limited to a sitting position.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(510(k) Number K061186