K041190

WELL SUCCESS BIOTECH. INC.

MAY 25 2004 6F, No.70, Zi You Road, Hsinchu City, 300, Taiwan, R.O.C.

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" 510(k) SUMMARY "

Submitter's Name: **WELL SUCCESS Biotech. Inc.**

6F, No.70, Zi You Road, Hsinchu City, 300, Taiwan, R.O.C.

Date summary prepared: April 30, 2004

Device Name:

Proprietary Name:	A&I Power Wheelchair, PC-401
	(Trade name: A&I, A&E, J&C)
Common or Usual Name:	Powered Wheelchair
Classification Name:	Powered Wheelchair, Class II, 21 CFR 890.3860

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The A&I Power Wheelchair, PC-401 is an indoor / outdoor Powered Wheelchair that is battery operated. It has a base with four-wheeled with a seat. The movement of the Wheelchair is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an onboard battery charger.

Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3: 1995 (Electrically Powered Wheelchairs, controller, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

SINON Power Wheelchair, SN-W401 (K040319)

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C.2 COMPARISON SUMMARY

(We place the related information for the predicate device in the following pages, including the visual appearance, 510k information on the FDA website, and the comparison and summary table.)

According to the above table that the intended use between two devices is the same. The **batteries** used are the same brand and similar U1 type that is certified by UL. The **control** systems for the two devices are same brand i.e., Dynamic types for the two devices. The **recharge** for the two devices are used the same resource, HP8204A, and the recharger is certified by UL. Besides, the **foldable frame**, removable **arm type**, same **warranty** on component and frame, **weight limit,** and **back upholstery** are the same material that also be passed the resistance ignition test by SGS.

The cruising range of the new device is 20~30 km and 32 km for the predicate device. This is mainly due to the fact that the new device uses smaller batteries. Certainly the real range depends on the practice environments, i.e., weight, surface, incline, and temperature. For the real life use, the two devices are substantially equivalent.

The maximum speed for the new device is 4.4 mph and 4 mph for the predicate device. The similar speed means the two devices shall also meet the relevant requirements for the braking time, distance, and dynamic stability for safety considerations. The different maximum speeds do not lead any safety considerations and they are substantially equivalent in this aspect.

The safety climbing abilities for the two devices are same 12°. Furthermore, we place the relevant specification of maximum climbing ability 12° in the owner's manual. The user's climb is not allowed to exceed 12° for the new device. In this sense the two devices are substantially equivalent.

To sum up the mainly different of the two devices are only appearance dimensions, i.e., the overall dimensions, the size of wheels, and seat dimensions. For the regular operator, these differences for the two devices do not lead to any performance differences, and the two devices are substantially equivalent.

Based on the above the information and the analysis, we know that the subject device, the predicate device have the same intended use the same technological aspects and only minor dimensions and material differences exist. We believe that FDA can decide the subject device and the predicate device are substantially equivalent.

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Summary for substantial equivalence comparison:

The electronic systems between two devices are the same and all passed by the UL certificated, for instance the electronic controller, batteries and recharge. Thus the same safety level for the two devices is assured. The major differences existing of the two Powered Wheelchairs are the different overall dimension and weight between the two devices. The overall appearance and weight differences are not safety aspect. So the new device is substantially equivalent to the predicate devices in this aspect.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2004

Well Success Biotech, Inc.
C/o Dr. Ke-Min Jen
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City, China (Taiwan) 300

Re: K041190
Trade/Device Name: A & I Power Wheelchair, PC - 401
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: April 30, 2004
Received: May 6, 2004

Dear Dr. Jen:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (K) NUMBER (IF KNOW): TBA

DEVICE NAME: *A&I Power Wheelchair, PC-401*

INDICATIONS FOR USE:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (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)

for Mark N Melkerson

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

510(k) Number K041190